HERMES DECLARATION
EXHIBIT 8

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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS
C.A. No. 04-12457 PBS

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TRAVEL TRANSCRIPT

DePUY MITEK, INC.,
a Massachusetts corporation,
Plaintiff,

v.

ARTHREX, INC.,
a Delaware corporation,
Defendant.

- - -

WEDNESDAY NOVEMBER 30, 2005

- - -

Oral deposition of DENNIS D. JAMIOLKOWSKI, taken pursuant to Notice, before Jeanne Cahill, RMR, CRR, at the offices of Woodcock Washburn, LLP, One Liberty Place, 33th Floor, 1650 Market Street, Philadelphia, Pennsylvania, commencing at 9:10 a.m.

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before.
A. I don't believe that I have.
Q. Can you look at the third page of the document where it says Supplemental Response to Interrogatory No. 6?
A. Yes, sir.
Q. Have you seen that response before, either in this form or some other form?
A. I don't believe I have, no.
Q. Could you read the first paragraph of that response?
A. Certainly.
"Supplemental Response to Interrogatory No. 6. Subject to its objections, based on information that is currently in its possession, and with the understanding that its investigation is still ongoing, DePuy Mitek further states that the claimed inventions were conceived at least as early as June 6, 1988, and reduced to practice at least as early as February 2, 1989, at Ethicon, Inc."
Q. You can stop there. I just want to ask you about that sentence.
A. Certainly.
Q. Does Ethicon agree with that sentence?
A. Yes.

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Q. And is June -- We talked earlier this morning about June 1988 is the document that you've seen that showed work at least as of that date?
A. That's right.
Q. It was June 6, that date, or that document?
A. Yes, sir.
Q. What specifically was conceived as of June 6, 1988?
A. That one could make a braided suture constructed of two or more fiber types designed to realize beneficial properties. The constructions specifically mentioned include PET, polytetrafluoroethylene combinations, PET and polypropylene, and an absorbable construction of PDS and Vicryl.
Four embodiments of this idea include carrier blending, and what that means is that you take the individual yarns that are placed on individual carriers during the construction. And a second method includes where the yarns of the two or more polymers are plied, the plies then resulting on carriers, and then those carriers used to make the braid.
It goes on to describe other ways of making composites, including fiber commingling, and the use of bicomponent fibers.

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To tell you the truth, I forgot what you asked me.
Q. Well, I asked you what was conceived.
A. And at the very least, that was conceived. And I've taken that off of the first page.
Q. First page of Defendant's Exhibit 35?
A. That is correct.
Q. And that's a document dated June 6, 1988?
A. June 6, '98 correct.
Q. 88?
A. '88.
Q. I caught you that time.
A. What is further conceived or what is further described are various combinations and various proposals for experiments to be done to help evaluate the merits of these ideas.
Q. I want to focus, my question was focused on what was conceived as of that date.
A. Okay.
Q. Now, you mentioned three combinations of materials, correct?
A. There were three combinations that were representative of the ideas, yes.
Q. The third one was the absorbable one?
A. That's correct.

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Q. And the absorbable one, that's the PDS/Vicryl?
A. That is correct.
Q. And am I correct that the PDS/Vicryl ultimately was not within the claims of the Hunter patent?
MR. BONELLA: Object to the form.
THE WITNESS: I believe that to be the case.
BY MR. SABER:
Q. The PET/PTFE combination, is that within the claims of the Hunter patent?
MR. BONELLA: Object to the form.
THE WITNESS: I believe that to be the case.
BY MR. SABER:
Q. The PET/PP combination, is that within the claims of the Hunter patent?
MR. BONELLA: Object to the form.
THE WITNESS: I believe that to be the case.
BY MR. SABER:
Q. What does PP stand for?
A. Polypropylene.
Q. What does PET stand for?
A. Polyethylene terephthalate.
Q. And what does PTFE stand for?
A. Polytetrafluoroethylene.
Q. And you told me about Vicryl earlier today, but what is PDS?

A. PDS is polyparadioxanone. It is an absorbable polyester. It has properties that are different than Vicryl. And it is as a -- it is used as a suture material, and that polymer is also used to make injection-molded implantable absorbable medical devices.
Q. Is the PET/PTFE combination non-absorbable?
A. That is correct.
Q. Is the PET/PP combination non-absorbable?
A. Correct.
Q. As of June 6, 1988, were any other combinations other than -- any other non-absorbable combinations other than PET/PTFE or PET/PP conceived by Ethicon?
A. I believe that the compositions that you mentioned were representative of an idea, which was laid out here. So those were specific embodiments that were mentioned, the idea being the combination of two or more yarns that were selected from different groups.
Q. Were there any specific combinations other than the two represented in Defendant's 35 that had been conceived as of June 6, 1988?
MR. BONELLA: Object to form. Asked and answered.
THE WITNESS: There are none that are recorded in Defendant's 35.
BY MR. SABER:

Q. Do you know of any? Does Ethicon know of any as of June 6, 1988, any specific combinations?
A. At the present time, I would say no.
Q. Now, there are four methods of --
A. Right.
Q. -- direct blending, is that the right word, the two yarns?
A. I certainly understand what you mean by that.
Q. Fine. Could you explain what method one is?
A. Certainly.
Q. Called carrier blending?
A. Correct.
In the course of producing a braid, that manufacturing process is easily conducted using a machine called a braider. Examples of this include a Butt braider, B-U-T-T, named after the company, I believe in Massachusetts.
The way this operation works or the way the equipment works is that a plate is provided in which gears are mounted which direct what are called carriers in serpentine fashion. These carriers carry yarn. They're, in fact, in spool form, and the fibers come off the spool.
So what you're doing is you're doing what every mother has done with a child with long hair, in terms of

braiding, providing an interconnection between the various yarns.
In the first method, again, called carrier braiding, a carrier will hold a yarn of a given type, let's call it A. Other carriers may contain A as well, but in this setup, at least one of the carriers is required to contain another type of yarn.
So in the diagram that's listed, there is an A and B, and in this case, it is A, A, B, A, A, B, B, indicating that these carriers then have either an A or a B.
Q. Am I correct that on each individual carrier, it's all of A or all of a B?
A. Yes.
Q. The method described in carrier blending, are braids made by that method part of the invention of the '446 patent?
A. Yes.
MR. BONELLA: Object to the form.
BY MR. SABER:
Q. Could you explain the second one?
A. Yes.
Q. Okay. What's called yarn blending.
A. In yarn blending, one would take a yarn, let's say it's A, and take another yarn, and let's say it's B.

They would be provided so as to meter out these yarns as supply spools onto another spool. This operation is called plying, P-L-Y-I-N-G.
These yarns can be combined with no twist, with what is called a Z twist, or what is called an S twist, the Z and the S depending upon whether it's right-handed or left-handed.
The subsequent spool containing the plied yarns is then used to supply the carrier spool. So an individual spool may contain a combination of Yarns A and B.
To read from the paperwork, Defendant's 35, yarn blending: "Blending is accomplished prior to the braiding by plying Yarns A and B together to form a composite yarn."
Q. Does that mean that each of the braids on the braider has a combination of A and B plied together?
A. No. You would wind up with only one braid. You used the wrong terminology.
Q. Okay.
A. A carrier may contain --
Q. Let me rephrase the question. Thank you.
A. Please.
Q. Would each carrier have an A and a B plied together?

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Q. If you could, on what's marked as Page 8 there, if you could read that last paragraph, and it flops over to the next page, I'm going to ask you a question or two about it.

A. "At least as early as June 6, 1988, the inventors conceived of the idea of a suture having a heterogeneous braid as claimed in the '446 patent.

"For example, Dr. Steckel's laboratory notebook describes the concept of a braided suture constructed of two or more fiber types designed to realize the beneficial properties of each polymer.

"Dr. Steckel's notebook further states that the composites be evaluated using PET/PTFE and PET/PP. As explained, the idea that the PET/PTFE and PET/PP combinations of yarns could be blended by carrier blending or dividing the yarns into two sets, Yarn A residing on one set and Yarn B on the other, having been developed.

"Dr. Steckel's notebook further describes various composite braids that were evaluated. They included a PET/PTFE braid and PET/PP braids that were carrier blended, as noted by CB.

"Dr. Steckel's notebook also describes the construction and evaluation of a braid that was formed with a carrier braider, and a braid of PTFE and PET.

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"Documents describing the chronology of the research and development include the documents bearing Bates Nos. DMI 002269-2678 and DMI 002199-2268."

Q. Thank you.

I want to ask you specifically about the sentence that talks about, "Dr. Steckel's notebook further describes various composite braids that were evaluated," and then goes on to say, "These included a PET/PTFE braid and a PET/PP braids that were carrier blended as denoted by CB."

A. Yes, sir.

Q. Looking back at Exhibit 37, the June 6, '88 document that we were discussing before the break, is there any disclosure of a PET/PP braid that was carrier blended as denoted by CB?

A. And the document you wish me to refer to is Document --

Q. Yes, the one that begins on 2617 from exhibit 37, and that entry goes on for four pages.

A. Got it. Okay.

And we're speaking of yarn blending of PET and polypropylene?

Q. Yes, sir. Is that shown in this document, and if so, where?

MR. BONELLA: When you say "document," just to

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clarify --

MR. SABER: The four-page June 6 document.

MR. BONELLA: All four pages?

MR. SABER: Yes, sir.

THE WITNESS: So starting with 2617, and CB -- carrier blending or yarn blending?

BY MR. SABER:

Q. Carrier blending. I think you said yarn blending.

A. You said yarn blending.

Q. Did I? I apologize if I did say yarn blending.

A. We don't want to have to take a walk.

Q. I meant to say carrier blending.

A. Okay. On those four pages of DMI 002617 to 2620, there are three carrier blending embodiments that were noted for evaluation, and the combinations were PET and polytetrafluoroethylene.

Q. That's PTFE?

A. PTFE. As well as a Vicryl/PDS combination. So as far as what you asked for PET/polypropylene, they were not part of the initial evaluation package.

Q. Do you know of any support for the statement that the braid -- that Dr. Steckel's notebook describes a combination braid being evaluated of PET/PP by the carrier blended method?

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A. I mean, I didn't see it in this document either. Is there anything else that I'm missing?

MR. BONELLA: What document are we talking about?

MR. SABER: The 6/6/88.

MR. BONELLA: The four pages?

MR. SABER: I didn't see it anywhere else, too, by the way, but it's not in the four pages, which is what the interrogatory is referring to.

MR. BONELLA: Object to the form of the question.

THE WITNESS: In terms of being specifically described on those four pages, I do not see any description. However, in the first paragraph of Page 2617, one includes PET/polypropylene combinations. And it's further stated that there are four methodologies that can be employed to combine these different fiber types, and carrier blending is one of the four ways of doing it.

So in terms of reading, on Page 2617, it certainly appears that PET/polypropylene combination by carrier blending is described.

BY MR. SABER:

Q. I understand, but as far as you can tell from this document, does this document ever show that such a

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HERMES DECLARATION
EXHIBIT 9

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc., a
Massachusetts Corporation,

Plaintiff,

vs.

CIVIL ACTION
NO. 04-12457 PBS

Arthrex, Inc., a Delaware
Corporation,

Defendant.
_________________________________/

DEPOSITION OF: DONALD GRAFTON

DATE: March 14, 2006

TIME: 8:38 a.m. to 1:23 p.m.

LOCATION: The Ritz Carlton Golf Resort
2600 Tiburon Drive
Naples, FL 34112

TAKEN BY: Plaintiff

REPORTER: Deborah A. Krotz, RPR, CRR

VIDEOGRAPHER: Gene Howell, CLVS

Q. Let me back up to make sure this is clear. Knot strength versus knot tiedown. In your mind, are they the same thing or are they different?
A. I'm not sure I understand your question. Say that again.
Q. Sure. Knot strength --
A. Mmm-hmm (affirmative).
Q. -- which I think you testified that you understood to be tying a knot in a suture and pulling it on a tensile machine -- tensile tester machine to determine the strength at which the knot will break; right?
A. Yes.
Q. Okay. Then there's another term called knot tiedown, and I'm trying to understand whether, in your mind, you think that's the same as knot strength or do you use that term to mean something else?
A. They're closely related.
Q. And how are they related?
A. When you have a knot tiedown, you've tied a knot. The strength of the knot is going to affect the ability to hold -- to approximate the tissue in the tiedown area that you're talking about.
Q. If the knot had a good tiedown or a bad tiedown, what do you mean by that?

A. Its ability to approximate the tissue and hold it in place through biomechanical forces.
Q. So that's related to knot strength, but it's not necessarily the same thing; is that the way you're using the term?
A. Yes.
Q. The way I heard you describe knot tiedown was you said the ability to approximate the tissue and hold it into place through biomechanical forces.
A. (Witness nods head affirmatively).
Q. When you say ability to approximate the tissue, what do you mean by that?
A. Shift tissue in the position that the surgeon would like for it to be on the bone.
Q. Shift tissue; did you say?
A. Yes.
Q. S-H-I-F-T?
A. Yes.
Q. So the knot's moving the tissue?
A. The suture is holding -- the suture loop with the knot in it, is holding the tissue in the position that the surgeon would like for it to be on bone.
Q. That's taking the place of the tissue? When you say approximate the tissue, how is it approximating tissue?

A. It's -- The tissue is here. The location the surgeon wants it here. The suture loop as it is tied moves the tissue into position.
Q. Holds it there?
A. Yes.
Q. And what -- what biomechanical forces were you referring to?
A. Forces on the glenohumeral joint.
Q. In a knot strength test, it's the forces are being applied and generally in one direction; correct?
A. Yes.
Q. The biomechanical force that you are referring to in this knot tiedown, the forces are coming from different directions; right?
A. Yes.
Q. Okay. When you are referring to knot tiedown then, you're referring to -- you're referring to it in a sense as a strength?
A. Are you finished? Is that the question?
Q. Right.
A. I don't believe -- Say it again then.
Q. Sure. Knot tiedown, the way you're referring to it, it's a strength then? It's kind of like -- because knot strength would be measured in p.s.i.
A. I said that's one of the attributes of it.

That's not the total attribute of it. I mean it's to approximate tissue into position is knot tiedown.
Q. Well, what else would be included?
A. I just told you. Approximate tissue, strength.
Q. So the strength would -- I understand the --
A. The size of the knot bundle. You know, there's --
Q. Size of the knot bundle?
A. Yes.
Q. What do you mean by that?
A. How large the knot is once it has been tied and cut.
Q. So knot tiedown includes the size of the knot bundle?
A. Yes. You know, the knot tiedown -- I want to say this -- that's not a term that we specifically use, so it's a little bit foreign. I mean I don't -- I've never had a surgeon ask me about knot tiedown.
Q. Okay.
A. So I didn't -- your -- I'm not sure where you're going with this, but there's -- we did knot testing and we did straight pull testing of the suture so that your knot tiedown, I'm -- I'm not real sure what you're asking for there. I --
Q. Well --

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A. I said they are related.
Q. Okay. They're your terms. I just want to understand them because when we ask questions, I want to make sure we're both on the same page, because there's a lot of terms that we're throwing around, and some people have different definitions and some people have different understandings of what they mean, so I want to know that when I ask you a question and I ask you a question about knot tiedown that we're both talking about the same thing so there's no misunderstanding what we're talking about.
A. I've told you they were closely related.
Q. Right. But closely related doesn't tell me what knot tiedown is in your mind, so I'm trying to figure out what it means in your mind. So now I've heard you say that it's the ability to approximate the tissue and hold it in place through biomechanical forces?
A. (Witness nods head affirmatively).
Q. I heard you say the size of the knot bundle is part of knot tiedown?
A. (Witness nods head affirmatively).
Q. And by size of the knot bundle, you are referring to how big the knot is when it's tied?
A. Correct.
Q. Anything else included within knot tiedown in your mind?

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A. Not that I can think of right now.
Q. Okay. So in evaluating the Tevdek suture, did you evaluate the Tevdek suture for knot tiedown characteristics?
A. Evaluated for knot strength and straight pull.
Q. How about knot tiedown characteristics?
A. There is no test report that would have knot tiedown as -- as part of the characteristics that were tested.
Q. You said there's no test report. And my question -- that does not necessarily answer the question.
MR. SOFFEN: I think he answered it no at the beginning of the answer.
Q. That's not what the record says.
A. I told you it was a term that we didn't use directly. Knot tiedown -- "knot tiedown" was not used. So the answer to your question then is no.
Q. No? Okay. How about the Pearsalls suture that was polyester? Was that evaluated for knot tiedown characteristics?
A. No.
Q. Okay. How about the term "knot security"? Are you familiar with that term?
A. Yes.
Q. What does knot security mean to you?

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A. The ability of the knot to not slip and to maintain the inner loop linear section that was tied with the knot and hold -- and maintain that during biomechanical forces without slippage.
Q. What do you mean by the inner loop linear section of the knot?
A. When you tie a knot, you're tying it most of the time to bone and tissue. There's -- If you tie a knot, then there's a loop; okay? The knot slippage would be measured as an increase in that loop diameter.
Q. Is there a standard test for that?
A. What do you mean standard test?
Q. A test -- Well, let me rephrase the question.
A. Is there any test for it? Or I don't understand the question.
Q. Let me rephrase the question. Was there a test that you are familiar with that you generally used to evaluate knot security?
A. Not generally. It was tested, but -- but not every time.
Q. And what test was that?
A. There -- the -- What test?
Q. Right.
A. The test for the slippage of the knot.
Q. And how was that test conducted?

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A. Pull tested with the inside i.d. of the suture held and measured the strength before the increase in size of the inner loop.
Q. What type of machine was used for that?
A. Tensile test machine.
Q. Would you draw a picture of that test.
A. (Witness complying).
Q. Okay. Can you label the components you've drawn.
A. (Witness complying).
Q. And can you describe what you have labeled -- I see you have labeled the crosshead, two hooks, the knot, and a suture loop; right?
A. Yes.
Q. Okay. And the forces applied by -- Well, what type of machine is this? I'm sorry. This is a tensile test?
A. Tensile test.
Q. And force is applied to pull from each direction, top and bottom, if you will?
A. That's what the two arrows signify.
Q. Okay. Are there mandrels which that knot -- around that suture loop? Does the suture loop go around mandrels?
A. Hooks or pins or some way to affix the suture. So when you say a mandrel, I mean there's a lot of

different types of mandrels.
Q. Okay.
A. I'm not sure what you mean.
Q. Something with a hook that the loop wraps around, goes around -- the suture loop goes around?
A. I've got two hooks listed there, yes.
Q. Okay. And you labeled the knot; right?
A. Yes.
Q. And this test is measuring -- Can you explain to me how this test is measuring --
A. Yeah, once the crosshead moves --
Q. Right.
A. -- this is placed under a fixed tension to start with to remove any -- any slack in the loop --
Q. Correct. Okay.
A. -- and then once it's test -- once the crosshead is moved, you measure the tensile strength which is required to increase that loop opening.
Q. Are you pulling on one of the parts of the knot?
A. That's what -- What do you mean parts of the knot? No. The knot's here on the side. Pulling 90 degrees from the knot on both ends.
Here, I'll draw you a bigger picture.
Q. Thank you.
A. (Witness complying).

Q. Well, the knot that you're describing here, is this knot the same knot as, for example, that you would tie your shoe? You just go over?
A. It's a square knot.
Q. You're calling it a square knot? Okay.
A. Yes. Now you can tie many different knots there.
Q. Right.
A. To determine which knot has the best efficiency with use with that particular type of suture -- there's 30 or 40 different types of knots.
Q. Okay.
A. The test calls for a square knot.
Q. Okay. And when the force is applied, it's measuring -- you want it -- the object here is to determine how much -- or I'm sorry -- the object is to determine when the suture that's tied in this knot starts slipping out of the knot?
A. Yes.
Q. And the force at which it does that is considered the knot -- it's the knot security?
A. Yes.
Q. Okay. Did you analyze the Pearsalls polyester suture for knot security?
A. Yes.
Q. How about the Tevdek suture? Did you analyze

that for knot security?
A. Yes.
Q. Okay. So in selecting sutures in your experience, knot security, knot strength, tensile strength are all important considerations?
A. Yes.
MR. SOFFEN: Are you going to label that as an exhibit?
MR. BONELLA: Sure. If you would date that and initial that, Mr. Grafton.
We'll mark that as DePuy Mitek Exhibit 421. And that's Mr. Grafton's drawing of the knot security test.
(DePuy Mitek Exhibit No. 421, Mr. Grafton's drawing of the knot security test, was marked for identification.)
Q. The Tevdek suture, was that also polyester?
A. Yes.
Q. And Size 2?
A. Yes.
Q. Any other sizes?
A. Possibly.
Q. But you don't remember?
A. No.
Q. Was the Tevdek suture braided?

A. Yes.
Q. Did the Tevdek suture have a core?
A. I have no idea.
Q. Why was there a shift -- Let me back up. When Arthrex began selling the Tevdek polyester suture, did it stop selling the Pearsalls polyester suture?
A. Yes.
Q. Why was there a shift from the Pearsalls polyester suture to the Tevdek polyester suture?
A. I answered that question already.
Q. You did? I'm sorry. I missed it. What was the reason?
A. The stiffness and compliance of the suture.
Q. So the Tevdek suture was more compliant --
A. That's correct.
Q. Let me finish the question. The Tevdek suture was more compliant than the Pearsalls polyester suture?
A. That's correct.
Q. Did the Tevdek suture have a coating?
A. Yes.
Q. Do you know what the coating was?
A. No.
Q. And the Pearsalls suture, was the braid constructed on a carrier braider machine?
A. Yes.

A. What's the date on this?
Q. The date on this is -- the last page is dated November 4th, 2005.
A. Okay. I want to quantify this then, because you're talking about a time period after I worked for the company, so when you -- when it says in here that I'm familiar with these products, it would be at the time I had left the company. And this is -- this was written after I left the company. So I can't totally say that I am familiar with those products under that.
Q. So you would agree that you were familiar with the state-of-the-art for surgical suture products as of the date you left Arthrex?
A. Define state-of-the-art, sir.
Q. State-of-the-art? Well, the general -- You don't have an understanding of what that means?
A. I want to understand what you mean in the context of this state-of-the-art.
Q. Okay.
A. I mean there's -- there's -- there's --
Q. This is from Pearsalls, so I can't tell you exactly what they mean, so ... Let me back up. When you were --
A. I was -- I was familiar with the competitive products on the market and what we offered and how they compared to the competitive products.

Q. Okay. And that was as of the date you left Arthrex?
A. Yes.
Q. Okay. And how long were you familiar with Arthrex's suture products and the competitive suture products that are in the marketplace?
A. When we started marketing the product, the sutures, until the time I left.
Q. Okay. So sometime when Arthrex began selling the suture from the supplier from New Mexico?
A. Yes.
Q. Okay. When Arthrex shifted from the Pearsalls suture to the Tevdek suture, was there any consideration to -- or for Arthrex designing its own suture?
A. No.
Q. Why not?
A. Because we could find a suture OEM that was available already. Why manufacture the suture when there's a readily available source?
Q. Now you said you tested for the Tevdek suture before it was selected; right?
A. Of course.
Q. And then it came back after it was selected, the response from surgeons was that it had low knot strength and tensile strength; right?

A. Yes.
Q. Didn't that come up in your testing?
A. I don't recall.
Q. What was your involvement in the development of FiberWire?
A. It was my idea.
Q. When you say it was your idea, what do you mean by that?
A. I'll give you -- Would you like the story on how FiberWire came about?
Q. Sure.
A. We were having issues from customers with the Tevdek suture being low tensile strength as compared to competitors' suture anchors with suture, primarily Ethicon.
Q. Ethibond?
A. Ethibond. This was numerous complaints from friendly surgeons, not -- not a massive amount of complaints, but it was determined that the tensile strength of the suture was not as good as the Ethicon Ethibond suture.
Q. When you say friendly, do you mean friendly to Arthrex?
A. Yes. And I had gotten a phone call from a Dr. Deberdino who was a surgeon at Fort Sam Houston, San Antonio. His -- his comments were that he had tied three knots the previous afternoon using the FASTak product of Arthrex -- that's a glenoid labrum device -- and had broke the knots on all three of them. And -- you know -- he said it kind of jokingly. He said, "And I didn't even work out the day before."

And so he was tying to be nice about it, but bottom line was your suture sucks. Okay?
And so -- you know -- we're in a position where we need to find a suture that will be competitive. I had been to Pearsalls many times working on bioabsorbable products. This was the time that you referred to earlier where I said three to five, and was familiar with suture manufacturing, the steps required to manufacture a suture.
One of the trips there, Mr. Lyon had pointed out to me a -- the other products they manufactured, which was fishing line and silk used in decorated drapes. The fishing line used a ultra-high molecular weight polyethylene material that was very strong, and I -- at some point, it was decided that we would try some of that for a suture.
I had Pearsalls, mainly through Brian, as being the manufacturing person --
Q. Brian Hallett?

A. That's correct -- make some Size 2 braided material, send to me, and at the -- coincidentally, at the same time, I had a Dr. Steve Burkhart from San Antonio and a Dr. Casey Chan, who is a R & D guy in knot testing and suture. They were -- they were at Arthrex at the time when this material showed up.

We tested the material. The strength was excellent. The knot slippage was very poor, would not hold a knot.

So at that point in time, it looked like we would not be able to use an alternative material of ultra-high molecular weight polyethylene because the slippage of the material -- because of the slippage of the material tested with Casey Chan -- Dr. Chan and Dr. Burkhart. And so at that point in time, the -- the product was -- was on hold.

I was on a trip to Chicago to the national sales meeting, and I had this idea of adding PET to the ultra-high molecular weight polyethylene to enhance the or reduce the knot slippage of the product. I sent an e-mail to Dr. Steve Burkhart and suggesting that since he was familiar with the testing we had done very recently with just the ultra-high molecular weight PE, of adding the PET, and his -- I'll never forget the e-mail. He thought that was a killer idea.

And so I had asked then at that time for Brian

Hallett to make me samples up of using those two materials and -- and send to me. And we tested the materials, and now we had a product that had superior tensile strength and greater knot strength than any competitive product out on the market.

Q. Okay. If I could just back up to a couple of points that you mentioned to make sure I understand what happened here. The -- You said the idea began -- or I'm sorry. Back up. You said when this idea came up, you had already been to Pearsalls several times?

A. Mmm-hmm (affirmative).

Q. And you were familiar with --

A. Yes.

Q. And when this idea came up, you were familiar with how sutures were manufactured?

A. Yes.

Q. Okay. And what did you mean by that?

A. One of the products -- projects that I worked on was a bioabsorbable suture similar to what Ethicon sells as Panacryl, and the difference being this was 100 percent PLLA material. The -- so we worked on this for about a year -- I don't know the exact time -- with many trips over to Pearsalls to change the construct of the yarn to enhance the tensile properties of the material. And so at that time, I became familiar with how a suture is

processed to make a braid.

Q. Okay. And how many times were you over in England?

A. I told you already. Three to five.

Q. Three to five.

A. Approximate.

Q. Is that total lifetime?

A. That's an approximate number total lifetime, yes.

Q. Have you been to other manufacturing facilities for sutures?

A. Jenzyme Tevdek.

Q. And how many times have you been there?

A. Once, I believe.

Q. And when you were at Jenzyme Tevdek, did you see the manufacturing processes for Tevdek?

A. It was a dog and pony quick courtesy through the facility.

Q. So when you came up with the idea for using ultra-high molecular weight polyethylene in a suture, did you -- you say you are familiar with how sutures are made?

A. I'm also a fisherman. There's -- you know -- fishing line is -- uses ultra-high molecular weight polyethylene as a material that's used for sport fishing, very high strength.

Pearsalls made fishing line. And so they had

this material already available as a fishing line. So it was an easy conversion -- you know -- conclusion, conversion to say what if this is used as a suture material, because ultra-high molecular weight polyethylene is a totally inert material.

Q. When you saw that Pearsalls had been using ultra-high molecular weight polyethylene in fishing line --

A. Yes.

Q. -- do you know how it was being used in fishing line, what the construction was?

A. No.

Q. Was it a braided construction? Was it --

A. I can't tell you for sure, sir.

Q. You don't know?

A. I wasn't interested in buying fishing line, so I didn't look at the details of it.

Q. So you had -- Sitting here today, you can't tell me anything at all about how the fishing line that Pearsalls was making with ultra-high molecular weight polyethylene was constructed?

A. It went through their manufacturing processes in their company, but specifically how it was made, the constructs, I have no idea or the size.

Q. In other words, you have no idea if it was all

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ultra-high molecular weight polyethylene or if it was braided or --
A. It's been too long ago. I can't tell you that.
Q. And your idea was to use the ultra-high molecular weight polyethylene as a suture?
A. Yes.
Q. Okay. And you had Mr. Hallett make a Size 2, I think you said?
A. Yes.
Q. Okay. Can you describe the construction of that first --
A. I don't remember now. It's been too long.
Q. Was it all ultra -- ultra-high molecular weight polyethylene?
A. Initially, yes, as a test prototype material.
Q. Was it braided?
A. Yes.
Q. Was it an eight-carrier or a sixteen-carrier?
A. I don't remember.
Q. You said it was a Size 2 though?
A. Yes.
Q. So it was a Size 2 ultra-high molecular weight polyethylene braided suture that did not have PET?
A. For the initial prototype material, that's correct.

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Q. Okay. And it didn't have nylon or any other material braided with it?
A. No.
Q. So the initial prototype was a ultra-high molecular weight polyethylene braided suture prototype, if you will?
A. Yes. Size 2.
Q. Size 2. And was the initial prototype, was it coated?
A. I don't remember.
Q. Okay. Do you know if the initial prototype went through any other manufacturing process like stretching or heating, twisting?
A. I don't recall.
Q. Was the initial prototype 100 percent ultra-high molecular weight polyethylene?
A. For the fourth time, yes.
Q. Okay. And you tested the initial prototype that was 100 percent ultra-high molecular weight polyethylene with Dr. Burkhart and Dr. Chen?
A. Dr. Casey Chen, correct.
Q. Okay. And the test that you conducted with Dr. Burkhart and Dr. Chen on the ultra-high molecular weight polyethylene was a knot strength test?
A. Knot security.

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Q. Knot security test?
A. Yes.
Q. Was that the test we drew in Exhibit Number 421?
A. That's correct.
Q. Okay. And you said the strength was excellent. I believe, of the initial prototype. but the knot slippage was poor; is that right?
A. Yes.
Q. Okay. When you say the slippage was poor of the initial prototype, what do you mean?
A. Less than the tensile strength capability of the existing Arthrex product.
Q. So the knot slippage was less than the Tevdek suture?
A. Yes.
Q. And it was -- knot slippage was such that it was determined that the 100 percent ultra-high molecular weight polyethylene suture prototype wasn't suitable to be developed?
A. That's correct. Yes.
Q. Okay. Ultra-high molecular weight polyethylene, you said the knot slippage was poor?
A. (Witness nods head affirmatively).
Q. Ultra-high molecular weight polyethylene, is that a lubricious material?

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A. Yes.
Q. And was the knot slippage of this ultra-high molecular weight polyethylene poor security because of the lubricity of polyethylene?
A. Yes.
Q. Yes?
A. Yes.
Q. So then you came up with the idea to braid PET with the ultra-high molecular weight polyethylene to reduce the knot slippage?
A. Yes.
Q. And when you say knot slippage, we're referring to this knot security test?
A. Yes.
Q. So are we using the terms knot slippage and knot security interchangeably here?
A. You are, yes.
Q. In your testimony?
A. Yes.
Q. So the knot security of the 100 percent ultra-high molecular weight polyethylene was poor, the prototype; right?
A. Yes.
Q. And your idea was to add the PET and to improve the knot security?

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MR. SOFFEN: Objection; asked and answered.
You've asked him the same thing multiple times. But you can answer.
A. I've lost count, it's been so many times, but the answer again is yes.
Q. Okay. And Dr. Burkhart said that was a killer idea?
A. What was a killer idea?
Q. The killer idea was that your idea of adding PED -- PET -- I'm sorry. I'll rephrase that question.
Did Dr. Burkhart say that your idea to braid PET with the ultra-high molecular weight polyethylene to improve knot security was a killer idea?
A. Yes.
Q. Okay. And then you said you had Pearsalls manufacture a prototype that had PET and ultra-high molecular weight polyethylene braided?
A. Yes.
Q. And you tested that prototype?
A. Yes.
Q. And you said that that prototype had good knot strength?
A. Correct.
Q. And the prototype of PET braided with ultra-high molecular weight polyethylene had good knot security?

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A. Yes.
Q. And the prototype of PET and ultra-high molecular weight polyethylene braided together also had good tensile strength?
A. Yes.
Q. And after you tested this second prototype, if you will, of the PET braided with ultra-high molecular weight polyethylene, was then the decision made to pursue trying to commercially develop this idea?
A. Yes.
Q. Did you -- when you made -- Who made the decision to go forward and try to commercialize this idea?
A. Myself and Reinhold, surgeons that we collaborated with, marketing people. You know, it wasn't just myself.
Q. Okay. Was this prototype that had the PET braided with the ultra-high molecular weight polyethylene, was it -- did it have a coating on it?
A. Yes.
Q. It did?
A. (Witness nods head affirmatively).
Q. And what was the coating?
A. I forget the name. It's like an MED2174s.
Q. That was on the prototype?
A. Which prototype are you referring to now?

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Q. I'm talking about the --
A. The second prototype with the PET?
Q. Correct.
A. Yes.
Q. The second prototype that had the coating on it?
A. Yes.
Q. And was that part of your initial idea, or was that -- because I thought you said your initial idea was to add the PET. Was it also to coat it, or was that something that came later?
A. If you're going to market the product, it needs the coating on it, sir.
Q. Okay. But the prototype that was manufactured that you asked --
A. Most likely, it was coated, because it needed to be as the final product would be marketed.
Q. You said most likely. Do you remember or you don't remember whether the prototype that had the PET and the ultra-high molecular weight polyethylene was coated?
A. I can't tell you for sure that it was at that prototype stage.
Q. Okay. Was this prototype that you had -- after you tested the prototype with PET with ultra-high --
A. Excuse me. I want to change that.
Q. Okay.

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A. I never got samples of constructions from Pearsalls without a coating unless I specifically asked for it not to be coated. So there's a very high probability that the suture came as -- the second prototype -- as coated.
Q. That was standard for them to coat it, in other words?
A. Yes.
Q. Okay. So the initial prototype that was ultra-high molecular weight polyethylene, did you ask for that not to be coated?
A. No.
Q. So chances are that that one was coated?
A. Quite possibly.
Q. After you tested the prototype of PET and ultra-high molecular weight polyethylene braided together, did you believe that it would then work as a suture?
A. Yes.
Q. Okay. Is there anything else you think you needed to do in order to determine whether it would work as a suture?
A. Yes.
Q. What did you need to do?
A. Biocompatibility toxicity testing, bioburden levels, all the design control GNP items that need to be

done on any product. Obviously, there needed to be a check -- there's a checklist -- okay -- so I'm going by memory, that it needed to be looked at from a patent standpoint to see if there was any infringing as well as whether the product was compatible, along with the GNP items that are required for the product.

Q. Okay. Those things you are describing to me, those were all kind of commercial considerations. My question is a little different. Maybe my question wasn't clear. My question was more along the lines of once you had the prototype of the ultra-high molecular weight polyethylene and PET braided together and you tested it and you believed that it would work as a suture, I understand there's things you needed to do to make it a commercial product.

Was there anything else you needed to do in your mind to clarify whether it needed to -- whether it could work as a suture?

A. We needed to have a surgeon look at it that would actually be tying knots with it to get their understanding of -- of how they felt about the suture.

Q. Okay. Anything else though?

A. Not that I recall.

Q. Okay.

MR. SOFFEN: Is it time for a break? In a few

minutes?

MR. BONELLA: Yeah. Just give me five. Let me just finish this line of questions.

Q. Was the initial prototype that was ultra-high molecular weight polyethylene, was that sterile?

A. I don't remember.

Q. How about the prototype that was PET and ultra-high molecular weight polyethylene braided together? Was that sterile?

A. I don't remember.

Q. Would it have to have been sterile? Would the prototypes have to have been sterile?

A. Not to test on the tensile test machine.

Q. Why not?

A. Because it's not going into a human. You don't -- The bioburden levels at that point is not a factor that was wrong.

Q. Was sterilization another process at that time? Was that something you really didn't have to account for?

A. Say the question again.

Q. I'm just making sure that what you're saying is that sterilization is just to -- was just to -- it's really for biocompatibility? It's not to change the properties of the material; is that right?

MR. SOFFEN: Objection; vague.

A. I don't know. I don't know. That's really a weird question.

Q. I understand you are saying they weren't sterile.

A. No. I didn't say -- I said I don't recall, sir.

Q. You don't recall?

A. Yes.

Q. Okay. And my question was would they have had to have been, and you said, I think, no because they were testing them for mechanical properties.

A. Yes.

Q. Okay. Did you -- Would the sutures have had to have been sterile when you tested them for mechanical properties?

A. I already answered that.

MR. SOFFEN: Objection; asked and answered.

A. I said no. It didn't have to be to be tested on a tensile test machine.

Q. And why is that?

A. I already answered that also. It's not being used for human or animal use, so the biocompatibility issues of the suture at that time were not looked at. The mechanical features of the suture were all that were looked at at that portion of the prototype stage.

Q. Did sterilization have a big effect on the mechanical properties of the suture, the tensile?

MR. SOFFEN: Objection.

A. I -- I can't answer that question.

Q. You don't know?

A. No.

Q. But when you made the decision to go forward with this, you can't remember whether they were sterile or not?

A. You asked me -- You're -- you're kind of putting a couple of things together, so that's why you're --

Q. Okay. Maybe I'm getting confused.

A. You asked me if the prototypes were sterile, and I said no.

Q. Okay.

A. The decision to go forward with the product, obviously, there has to be sterilization done before the product can be marketed.

Q. Absolutely. And are you saying that the decision to go forward with it was made before you tested a sterile product?

A. I can't say that.

Q. Do you recall testing a sterile product before the decision was decided to make -- decided to go forward with the PET and the --

A. I don't remember.

Q. -- ultra-high molecular weight polyethylene?

A. I don't -- It depends on what point in time you

A. I don't recognize this particular exhibit, but it looks like a test report.
Q. Is that your signature on the first page?
A. Yes, it is.
Q. And you signed it on February 13th, 2003?
A. Right.
Q. And the test objective stated was to evaluate US -- I'm sorry -- FiberWire US 3/4 sutures, construction numbers DTPS 21 and DTPS 34 for knot pull, straight pull, and diameter. Do you see that?
A. Yes.
Q. And the previous exhibit, 175, refers to DTPS 21 and 34 and that was in January of '03; right?
A. Yes.
Q. Okay. Looking at Exhibit 422, does that refresh your memory at all as to why Arthrex was evaluating a 100 percent polyester -- I'm sorry. I will rephrase the question.
Looking at Exhibit 422, does that refresh your memory at all as to why Arthrex was evaluating a construct that had 100 percent polyester in the sheath?
A. I don't remember.
Q. You don't remember? In the Observations and Conclusions section of Exhibit 422 on the front, it said, "Also, both the sutures had similar strength in straight

pull, but knot pull const. DTPS 34 had more strength than DTPS 21. Hence, only construction DTPS 34 is approved for production." Do you see that?
A. Yes.
Q. Do you recall reaching that conclusion?
MR. SOFFEN: Objection. There's no evidence that it's Mr. Grafton's conclusion here, but ...
MR. BONELLA: It's coming.
A. I don't remember the circumstances of this document, so I can't really answer that.
Q. Would you turn to Page ARM 25664.
A. Is that in this document?
Q. Yes. In Exhibit 422. Do you see it's a Pearsalls Limited Certificate of Conformity?
A. Yes.
Q. Do you see that?
A. Yes.
Q. Do you recall seeing these types of documents before from Pearsalls?
A. Yes.
Q. What was your understanding of the purpose of a Certificate of Conformity that Pearsalls would send?
A. It's a cert that goes with the product to give the certifications of how it was tested and what the conformance of it is.

Q. And that's according -- and those certs are according to the U.S. Pharmacopeia?
A. Yes.
Q. Now does Pearsalls sterilize the products for Arthrex?
A. No.
Q. So these Certificates of Conformity are issued without sterilization?
A. That's correct. In this particular one, yes.
Q. In general, were the Pearsalls --
A. In general, Pearsalls, yes. That was -- that was prior to sterilization when we received the product from Pearsalls.
Q. Did Arthrex do a new Certificate of Conformity after the products have been sterilized?
A. It was tested after sterilization.
Q. Does Arthrex do a new Certificate of Conformity?
A. There was quality control records that would show the test result after sterilization.
Q. And how were those tests -- how were those tests done?
A. Same type of tests, knot, straight pull.
Q. Okay. And were they done for each batch of FiberWire, or did you select a certain sample from each batch? Like how were the tests done after sterilization?

A. Early on, I'm sure every batch was done. After that, probably not every batch.
Q. Do you recall the results of those tests?
A. No.
Q. What type of sterilization procedure does Arthrex use for FiberWire?
A. ETO and gamma.
Q. And those are known procedures? Are they -- I will ask a better question.
Did Arthrex develop those procedures, the sterilization of ETO and gamma, or were those known procedures in the art?
A. What do you mean by known? ETO and gamma are sterilization methods used in medical products. If that's your definition of known, the answer to that is yes.
Q. Did Arthrex develop anything special about applying those techniques to FiberWire?
A. They depended on how the product was sold. Whether it was sold in an envelope or with a suture anchor, there would be different types of sterilization that Arthrex would have been involved in the development.
Q. What do you mean by depending upon the -- how the product was sold?
A. Whether it was sold with a suture anchor, metal or bioabsorbable, those require different types of

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uncoated but that had gone through the scouring and dye process?
A. I don't remember.
Q. When you tested the coated versus uncoated, do you know whether the coated one that you tested was one that had been dyed --
A. I don't remember that.
Q. -- or undyed? Okay. If it's a -- Okay. Do you recall like any invoices that came back with the samples that you asked for for testing in relation to the Ethicon patent?
A. No. There may not have been invoices.
Q. Do you see inside these packages, there's -- it looks like, at least for this one --
A. Ah, okay. Here. You see this little round section?
Q. Yes.
A. This is most likely the information that was on the round 2-inch spool.
Q. Okay.
A. And this is where somebody xeroxed it on the machine, it looks like, and cut it out, the silhouette of it, and that's what we're looking at there, now that I see it closer.
Q. Okay. Do you see where it says batch? Coated

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MED. At least this one says Coated MED. And it says Batch on it. And it's Exhibit 428.
A. I see the information, yes.
Q. Okay. Do you see the uncoated one has a -- it has a batch number there. Do you see that for the uncoated?
A. Yes.
Q. Is that a Pearsalls batch number?
A. Yes.
Q. And do you see the other number there? There's a -- on the -- it has the number 38A500500? Do you see that number?
A. Yes.
Q. Do you recognize that number?
A. No. It's not an Arthrex number.
Q. Okay. How about the L51211 number? Do you recognize that number?
A. No. Those are all Pearsalls' internal numbers.
Q. Okay. Did you keep any records of the samples that you got from Pearsalls for testing uncoated versus uncoated with respect to the 44 -- with respect to the Ethicon patent of how the samples were to be maintained or kept?
A. I'm sure I turned the samples over to our test group. I don't recall any -- and probably any certs or

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information that were with them, but I didn't keep any of that.
Q. Okay. When you say you turned them over to the test group, do you mean when you left or was that when you completed the coated versus uncoated testing that you did?
A. At the time that the testing was to be done, I would give them the samples and the certifications so they would know which is coated and which is uncoated.
Q. Okay. And did you get the samples back after the testing, or did they remain with the test group?
A. I don't remember.
Q. Okay. I think the question kind of came out fuzzy. I have to reask one of the questions. I misspoke.
Did you keep any records of the samples that you got from Pearsalls for testing coated versus uncoated with respect to the Ethicon patent?
A. Keep any copies of the records?
Q. Yeah.
A. The test results?
Q. No, the records in terms of maintaining the samples, of how the samples were to be maintained or --
A. I turned all of that over to the test department.
Q. Okay.
A. Because they would need that to be able to write up the test report, any information I had.

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Q. Do you know if any of the samples that -- when you tested the coated versus uncoated in relation to the testing for the Ethicon patent, had any of those undergone sterilization?
A. I don't think they had.
Q. Okay. Now in the coating process that Pearsalls uses, there's an oven, and there's some tension applied during that process?
A. Yes.
Q. Right? Do you know if the uncoated sample that you tested in relation to the Ethicon patent had undergone that heat process and the tensioning?
A. They both -- The coated or both?
Q. No, the uncoated.
A. Uncoated?
Q. Right.
A. I'm sure it did not.
Q. Okay.
A. When you are saying heat process, it's to flash off the solvents with -- with the amount of heat is used for.
Q. Are you aware of the temperatures that are used?
A. No.
Q. Are you aware of how long the FiberWire is in the ovens?

A. I have seen their equipment, and it's approximately a 50-foot long zoned oven.

Q. Do you know how fast the FiberWire is moving through there?

A. I -- At one time, I had that information, but I don't recall what it is now, how many feet per minute went through.

Q. Have you ever done any analysis as to whether that heating process and the -- whatever tension is applied has any effect on the material properties of the suture?

A. Well, it's hard to separate that from the coating, because the coating is -- what you're trying to accomplish there is put the coating on it which increases the lubricity of the product.

Q. Right.

A. So that that's not separated.

Q. Okay. Now the tests that you did or that you -- well, what was -- There was a test done in relation to this Ethicon patent of a coated versus an uncoated sample; right?

A. Yes.

Q. Do you recall that test?

A. To some extent. I know the people that worked on it.

Q. Okay. Did you personally witness the test?

A. I think I went back there a couple of times, but I don't remember the test that well.

Q. Okay. I just wanted to know whether you -- not necessarily whether you remember the test, but whether you personally witnessed it being done or you just kind of saw the results?

A. Well, it was over a long period of time, and I was in and out of the test lab.

Q. Okay.

A. So I did not witness the total time that the suture was being tested.

Q. What do you mean by over a long period of time?

A. A couple of days. It takes a while to set up fixtures and get the test working so that you can see the results.

Q. Okay. The testing that you saw --

A. It was a new test that we had never done before, so it's -- you know -- it takes a while to be able to get your test set up correctly.

Q. Okay. So you were involved in designing the test?

A. Ashley -- to some extent. I think Ashley and James Thomas were probably the two that were more involved with it.

Q. Okay. And --

A. I was more involved with determining the test samples and what we were looking for as a theorem at that time to -- to determine the difference between the two.

Q. And what were you -- what were you looking for? What was the theorem?

A. That adding the coating increased the lubricity of the suture.

Q. Okay. And so you -- You were involved to some extent in helping them to design this test to prove that point?

A. I explained that already. I was involved in providing the samples --

Q. Okay.

A. -- and what we were looking for. And how it was set up -- you know -- I don't recall any specific things that I told them to do there.

Q. Okay. So did you -- so did you approve the test --

A. Yes.

Q. -- before it was conducted?

A. Yes.

Q. Okay. And then you looked at the results afterwards?

A. Yes.

Q. And what did you conclude from the results?

A. That the coated suture increased the lubricity of the suture.

Q. Okay. And did you convey that to Mr. Soffen?

A. Yes.

Q. Did you convey any other results to Mr. Soffen in this testing of the coated versus uncoated samples?

A. I don't recall.

Q. Okay. How about Mr. John Schmieding? Did you convey to him the results?

A. I'm sure he was -- knew the results also.

Q. And the results being that the lubricity of the coating affected the lubricity of the product?

A. Increased the lubricity.

Q. Increased the lubricity. Okay.

Now you said the hypothesis or theorem was to test for coating effects? Is that -- Am I saying that right? I'm not trying to put words in your mouth. I'm just trying to set up a foundation for the next question.

A. To see if there was a difference.

Q. Okay.

A. And to be able to measure the difference.

Q. Okay. And who -- whose idea was it to do that?

A. I don't recall.

Q. Okay. Do you know -- Did Mr. Soffen tell you

HERMES DECLARATION
EXHIBIT 10

ENCYCLOPEDIA OF POLYMER SCIENCE AND ENGINEERING

VOLUME 10

**Molecular Weight Determination
to
Pentadiene Polymers**

A WILEY-INTERSCIENCE PUBLICATION
John Wiley & Sons
NEW YORK • CHICHESTER • BRISBANE • TORONTO • SINGAPORE

Library of Congress Cataloging in Publication Data:
Main entry under title:

Encyclopedia of polymer science and engineering.

Rev. ed. of: Encyclopedia of polymer science and technology. 1964–
"A Wiley-Interscience publication."
Includes bibliographies.
1. Polymers and polymerization—Dictionaries.
I. Mark, H. F. (Herman Francis), 1895–
II. Kroschwitz, Jacqueline I. III. Encyclopedia of polymer science and technology.

TP1087.E46 1985 668.9 84-19713
ISBN 0-471-80942-X (v. 10)

Printed in the United States of America

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NOMENCLATURE

Nomenclature, as used in this article, refers to the naming of polymeric materials. The nomenclature of scientific communication is emphasized, although there is generally little reason for differences between scientific and other, eg, commercial, usage.

Since the publication of the first edition of this Encyclopedia, the International Union of Pure and Applied Chemistry (IUPAC) has established the Commission on Macromolecular Nomenclature, which is now the leading nomenclature body in the polymer field. The Commission is promulgating a series of rules and definitions that are placing polymer nomenclature on a much more systematic basis than had previously been the case (Table 1) (1–21). The International Standardization Organization (ISO), primarily through its Technical Committee TC/61 Plastics, and various national nomenclature bodies (such as that of the American Chemical Society) are also helping to shape the field. Recent issues of *Chemical Abstracts* are additional authoritative sources of polymer nomenclature.

At the present time, the IUPAC Commission on Macromolecular Nomenclature is developing a set of definitions for many of the basic terms dealing with polymer molecules, assemblies of polymer molecules, polymer solutions, polymer crystals, polymer melts and solids, polymerization reactions, etc. It is also extending existing nomenclature to more complicated cases, such as cross-linked polymers. When this phase of the work is completed by the late 1980s, the naming of polymers and polymer terminology will have become largely systematized and, following the IUPAC practice in other fields of chemistry, a compendium of polymer nomenclature rules will be published.

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Table 1. IUPAC Publications on Polymer Nomenclature

Title	Comment	Refs.
Report on Nomenclature in the Field of Macromolecules	obsolete	1
Report on Nomenclature Dealing with Steric Regularity in High Polymers	superseded by Ref. 2	3
Revised Report on Nomenclature Dealing with Steric Regularity in High Polymers	superseded by Ref. 4	2,5
Report of the Committee on Nomenclature of the International Commission on Macromolecules	obsolete	6
Basic Definitions of Terms Relating to Polymers		7,8
List of Standard Abbreviations (Symbols) for Synthetic Polymers and Polymer Materials (1974)	superseded by Ref. 9	10
Use of Abbreviations for Names of Polymeric Substances	Recommendations 1986	9
Nomenclature of Regular Single-Strand Organic Polymers		11
Stereochemical Definitions and Notations Relating to Polymers	Provisional Recommendations 1980	12 4
Nomenclature for Regular Single-Strand and Quasi Single-Strand Inorganic and Coordination Polymers	Provisional Recommendations 1984	13 14
Note on the Terminology for Molar Masses in Polymer Science		15–17
Source-Based Nomenclature for Copolymers		18
Definitions of Terms Relating to Individual Macromolecules, Their Assemblies, and Dilute Polymer Solutions		19
Definitions of Terms Relating to Crystalline Polymers		20
A Classification of Linear Single-Strand Polymers		21

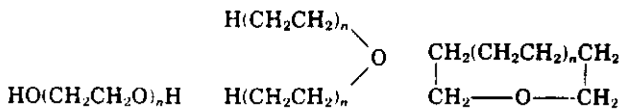
Basic Definitions

No nomenclature document is more fundamental to a given science than the definitions of basic terms used in that area. The IUPAC Commission on Macromolecular Nomenclature published a document in 1974 (8) that offers definitions of 52 terms, including polymer, constitutional unit, monomer, polymerization, regular polymer, tactic polymer, block polymer, graft polymer, monomeric unit, degree of polymerization, addition polymerization, condensation polymerization, homopolymer, copolymer, bipolymer, terpolymer, copolymerization, and many others. Both structure-based and process-based definitions are given.

Source-based Nomenclature

Traditionally, polymers have been named by attaching the prefix poly to the name of the real or assumed monomer (the "source") from which it is derived.

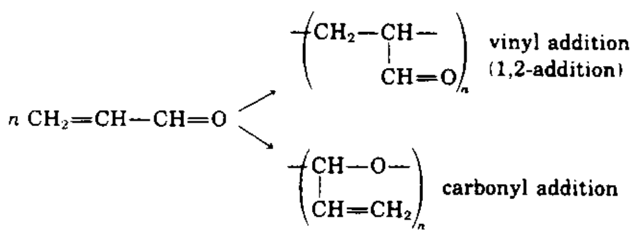
Thus polystyrene is the polymer made from styrene and will often be found in an index under "styrene, polymer of." When the name of the monomer consists of two or more words, parentheses should be used (1), as in poly(vinyl acetate), poly(methyl methacrylate), poly(sodium styrenesulfonate), etc. Failure to use parentheses can lead to ambiguity: polychlorostyrene can be the name of either a polychlorinated (monomeric) styrene molecule or a polymer derived from chlorostyrene; polyethylene oxide can refer to polymer (**1**), polymer (**2**), or the macrocycle (**3**).



(**1**) (**2**) (**3**)

These problems are easily overcome with parentheses; names such as poly(chloro)styrene, poly(chlorostyrene), and poly(ethylene oxide) clearly indicate the part of the name to which the prefix poly refers. The omission of parentheses is, unfortunately, quite common.

The principal deficiency of source-based nomenclature is that the chemical structure of the monomeric unit in a polymer is not identical with that of the monomer, eg, $—CH_2—CHX—$ vs $CH_2{=}CHX$; thus the name polymonomer is actually a misnomer. The structure of the repeating unit is also not specified in this scheme; for example, polyacrolein does not indicate whether the vinyl or the aldehyde group has polymerized (see ACROLEIN POLYMERS).



Different types of polymerization can take place with many other monomers, depending on the polymerization conditions. Furthermore, a name such as poly(vinyl alcohol) refers to a hypothetical source, since this polymer is obtained by hydrolysis of poly(vinyl acetate). In spite of these serious deficiencies, source-based nomenclature is still firmly entrenched in industrial literature and, to a lesser extent, in scientific communication. It originated at a time when polymer science was less developed and the structure of most polymers ill-defined. The rapid advances now being made in structural determination of polymers will gradually shift the emphasis of polymer nomenclature away from starting materials and toward the structure of the macromolecules.

Copolymers. Copolymers are polymers that are derived from more than one species of monomer (8). Because this is a process-based definition, source-based nomenclature can be easily adapted to the naming of copolymers (18). However, the arrangement of the various types of monomeric units must be specified. Seven types of arrangements have been defined and are shown in Table 2, where A, B, and C represent the names of monomers. The monomer names are linked through a connective (infix), such as *-co-*, to form the name of the copolymer, as in poly(styrene-*co*-acrylonitrile). The order of citation of the mono-

mers is arbitrary, except for graft copolymers where the backbone monomer is named first.

An equally acceptable alternative scheme utilizes the prefix copoly followed by citation of the names of the monomers used, separated from each other by an oblique stroke. Parentheses are also needed. For example, copoly(styrene/butadiene) denotes an unspecified copolymer of styrene and butadiene. The other connectives of Table 2 are placed before such names to provide additional structural information, as in

stat-copoly(styrene/butadiene)
ran-copoly(ethylene/vinyl acetate)
alt-copoly(styrene/maleic anhydride)
per-copoly(ethylene phenylphosphonite/methyl acrylate/carbon dioxide)
block-copoly(styrene/butadiene/methyl methacrylate)
graft-copoly(styrene/butadiene)

It is not necessary to use parentheses to enclose vinyl acetate, maleic anhydride, methyl acrylate, etc, even though the name of each of these monomers consists of two words; the names of the polymers, as written here, are unambiguous.

The names of copolymers, derived either from the main scheme or the alternative, can be further modified to indicate various structural features. For example, the chemical nature of end groups can be specified as follows:

α-X-ω-Y-poly(A-*alt*-B)
α-butyl-ω-carboxy-*block*-copoly(styrene/butadiene)

Whereas subscripts placed immediately after the name of the monomer or the block designate the degree of polymerization or repetition, mass and mole fractions and molar masses, which in most cases are average quantities, are expressed by placing corresponding figures after the complete name of the copolymer. The order of citation is as for the monomeric species in the name. Unknown quantities are designated by a, b, etc. Some examples follow.

A block copolymer containing 75 mass % of polybutadiene and 25 mass % of polystyrene is

polybutadiene-*block*-polystyrene (0.75:0.25 w) or
block-copoly(butadiene/styrene) (75:25 mass %)

A graft copolymer, consisting of a polyisoprene backbone grafted with isoprene and acrylonitrile units in an unspecified arrangement, containing 85 mol % of isoprene units and 15 mol % of acrylonitrile units is

polyisoprene-*graft*-poly(isoprene-*co*-acrylonitrile) (0.85:0.15 x) or
graft-copoly[isoprene/(isoprene;acrylonitrile)] (85:15 mol %)

A graft copolymer consisting of 75 mass % of polybutadiene with a relative molecular mass of 90,000 as the backbone and 25 mass % of polystyrene in grafted chains with a relative molecular mass of 30,000 would be

polybutadiene-*graft*-polystyrene (75:25 mass %; 90,000:30,000 M_r)

Table 2. IUPAC Nomenclature of Copolymers[a]

Type	Arrangement of monomeric units	Structure	Connective	Example
unspecified	unknown or unspecified	(A-*co*-B)	-*co*-	poly[styrene-*co*-(methyl methacrylate)]
statistical	obeys known statistical laws	(A-*stat*-B)	-*stat*-	poly(styrene-*stat*-acrylonitrile-*stat*-butadiene)
random	obeys Bernoullian statistics	(A-*ran*-B)	-*ran*-	poly[ethylene-*ran*-(vinyl acetate)]
alternating	alternating sequence	$(AB)_n$	-*alt*-	poly[(ethylene glycol)-*alt*-(terephthalic acid)]
periodic	periodic with respect to at least three monomeric units	$(ABC)_n$ $(ABB)_n$ $(AABB)_n$ $(ABAC)_n$	-*per*-	poly[formaldehyde-*per*-(ethylene oxide)-*per*-(ethylene oxide)]
block	linear arrangement of blocks	—AAAAA—BBBBBB—	-*block*-[b]	polystyrene-*block*-polybutadiene
graft	polymeric side chain different from main chain[c]	—AAAAAAAAAAAA— | B B B B B |	-*graft*-[d]	polybutadiene-*graft*-polystyrene

[a] Main system of the IUPAC document (18); an alternative scheme is described in the text.
[b] The connective -*b*- has also been used.
[c] Main chain (or backbone) is specified first in the name.
[d] The connective -*g*- has also been used.

A graft copolymer in which the polybutadiene backbone has a DP of 1700 and the polystyrene grafts have an unknown DP is named

graft-copoly(butadiene/styrene) (1700:*a* DP)

The published IUPAC copolymer document (18) should be consulted for the names of more complex copolymers, eg, those having a multiplicity of grafts or having chains radiating from a central atom (see also BLOCK COPOLYMERS; COPOLYMERS, ALTERNATING; COPOLYMERIZATION; GRAFT COPOLYMERS).

Structure-based Nomenclature

For organic polymers that are regular, ie, have only one species of constitutional unit in a single sequential arrangement, and consist only of single strands, the IUPAC has promulgated a structure-based system of naming polymers (11). As originally devised by the Polymer Nomenclature Committee of the American Chemical Society (22), it consists of naming a polymer as poly(constitutional repeating unit), wherein the repeating unit is named as a bivalent organic radical according to the usual nomenclature rules for organic chemistry. It is important to note that in structure-based nomenclature the name of the constitutional repeating unit has no relationship to the source from which the unit was prepared. The name is simply that of the largest identifiable unit in the polymer, and locants for unsaturation, substituents, etc are dictated by the structure of the unit.

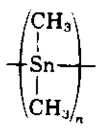
The steps involved in naming the constitutional repeating unit are (*1*) identification of the unit, taking into account the kinds of atoms in the main chain and the location of substituents; (*2*) orientation of the unit; and (*3*) naming of the unit. Examples of names for some common polymers are given in Table 3. Note that in this system parentheses are always used to enclose the repeating unit.

Structure-based nomenclature can be utilized to name polymers with great complexity, provided only that they be regular and single-stranded. Among these are polymers with constitutional repeating units which consist, themselves, of a series of smaller subunits; polymers with heteroatoms or heterocyclic ring systems in the main chain; and polymers with substituents on acyclic or cyclic subunits of constitutional repeating units. Structure-based nomenclature is also applicable to copolymers having a regular structure, regardless of the starting materials used, eg, poly(oxyethyleneoxyterephthaloyl). In principle, it should be possible to extend the existing structure-based nomenclature beyond regular, single-strand polymers to polymers that have reacted, cross-linked polymers, ladder polymers, and other more complicated systems.

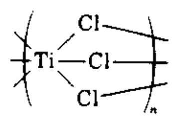
Structure-based nomenclature has gained acceptance in the scientific literature, eg, *Chemical Abstracts*, because it overcomes many of the deficiencies of source-based nomenclature.

Inorganic and Coordination Polymers. The nomenclature of regular single-strand inorganic and coordination polymers (qv) is governed by the same

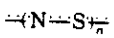
ındamental principles as that for single-strand organic polymers (14). The name f such a polymer is that of the smallest structural repeating unit prefixed by ne terms poly, *catena* (for linear chains) or other structural indicator, and des-ṛnations for end groups. The structural units are named by the nomenclature ıles for inorganic and coordination chemistry. Some examples are



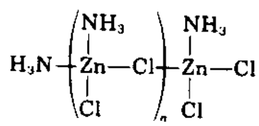
catena-poly[dimethyltin]



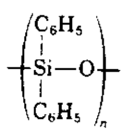
catena-poly[titanium-tri-μ-chloro]



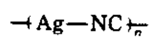
catena-poly[nitrogen-μ-thio]



α-ammine-ω-(amminedichlorozinc)-*catena*-poly[(amminechlorozinc)-μ-chloro]



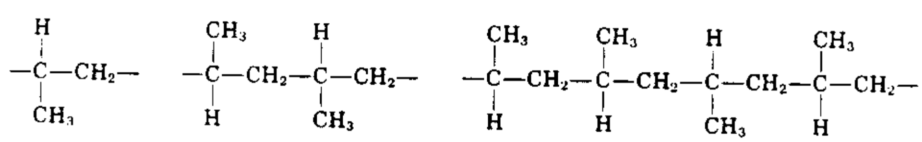
catena-poly[(diphenylsilicon)-μ-oxo]



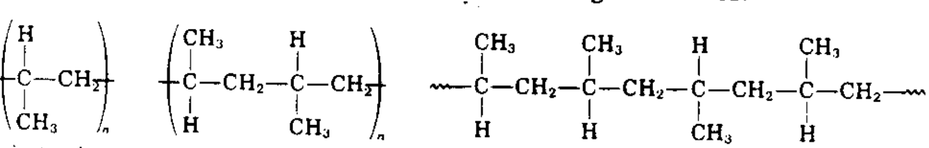
catena-poly[silver-μ-(cyano-*N*:*C*)]

Stereochemical Definitions and Notations. Structure-based nomenclature regular polymers (4) can denote stereochemical features if the repeating unit ed is the configurational unit, ie, a constitutional unit having one or more sites defined stereoisomerism (8). Structure-based names are then derived in the ual fashion. The various stereochemical features that are possible in a polymer ıst be defined.

Natta and co-workers introduced the concept of tacticity, ie, the orderliness he succession of configurational repeating units in the main chain of a polymer. r example, in poly(propylene), possible steric arrangements are shown in Fischer jections displayed horizontally:



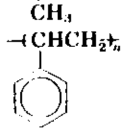
d the corresponding polymers have the following structures:

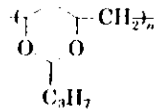
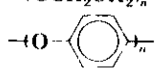
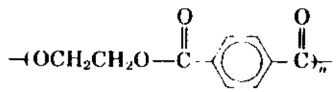
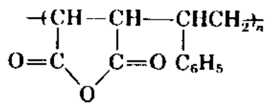


isotactic syndiotactic atactic

The isotactic polymer has only one species of configurational unit in a single uential arrangement and the syndiotactic polymer shows an alternation of figurational units that are enantiomeric, whereas in the atactic polymer the

Table 3. Examples of Systematic Structure-based Names for Polymers[a]

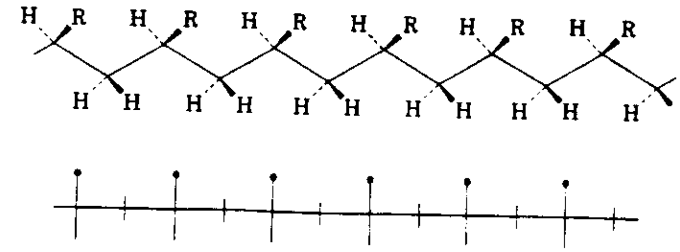
Structure	Structure-based name	Common (source-based) name
$-(CH_2CH_2)_n-$	poly(methylene)	polyethylene
$-(\underset{\displaystyle CH_3}{\underset{\mid}{C}}HCH_2)_n-$	poly(propylene)	polypropylene
$-(\overset{\displaystyle CH_3}{\overset{\mid}{\underset{\displaystyle CH_3}{\underset{\mid}{C}}}}-CH_2)_n-$	poly(1,1-dimethylethylene)	polyisobutylene
$-(\underset{\displaystyle CH_3}{\underset{\mid}{C}}{=}CHCH_2CH_2)_n-$	poly(1-methyl-1-butenylene)	polyisoprene
	poly(1-phenylethylene)	polystyrene
$-(\underset{\displaystyle Cl}{\underset{\mid}{C}}HCH_2)_n-$	poly(1-chloroethylene)	poly(vinyl chloride)
$-(\underset{\displaystyle CN}{\underset{\mid}{C}}HCH_2)_n-$	poly(1-cyanoethylene)	polyacrylonitrile
$-(\underset{\displaystyle OOCCH_3}{\underset{\mid}{C}}HCH_2)_n-$	poly(1-acetoxyethylene)	poly(vinyl acetate)
$-(\overset{\displaystyle F}{\overset{\mid}{\underset{\displaystyle F}{\underset{\mid}{C}}}}CH_2)_n-$	poly(1,1-difluoroethylene)	poly(vinylidene fluoride)

$\mathrm{-\!\!(CF_2CF_2)\!\!-_n}$	poly(difluoromethylene)	polytetrafluoroethylene
	poly[(2-propyl-1,3-dioxane-4,6-diyl)methylene]	poly(vinyl butyral)
$\mathrm{-\!\!(C(CH_3)(COOCH_3)-CH_2)\!\!-_n}$	poly[1-(methoxycarbonyl)-1-methylethylene]	poly(methyl methacrylate)
$\mathrm{-\!\!(OCH_2CH_2)\!\!-_n}$	poly(oxyethylene)	poly(ethylene oxide)
	poly(oxy-1,4-phenylene)	poly(phenylene oxide)
	poly(oxyethyleneoxyterephthaloyl)	poly(ethylene terephthalate)
$\mathrm{-\!\!(NH-C(=O)(CH_2)_4C(=O)-NH(CH_2)_6)\!\!-_n}$	poly(iminoadipoyliminohexamethylene)	poly(hexamethylenediamine-*co*-adipic acid) or poly(hexamethylene adipamide)
	poly[2,5-dioxotetrahydrofuran-3,4-diyl(phenylethylene)]	poly(maleic anhydride-*co*-styrene)

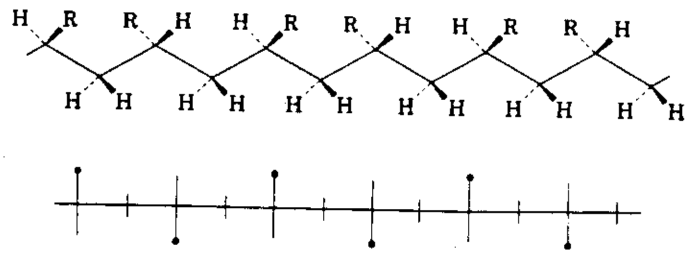
[a] Ref. 6. Courtesy of *Pure and Applied Chemistry*.

molecules have equal numbers of the possible configurational units in a random sequence distribution. This can be generalized as follows:

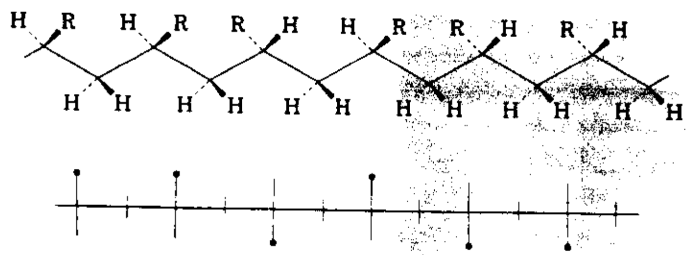
Isotactic:



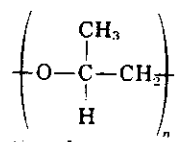
Syndiotactic:

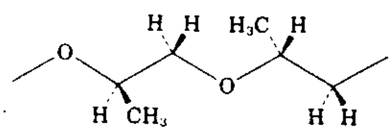


Atactic:

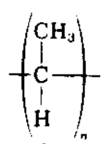


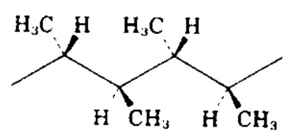
Further examples of tactic polymers are



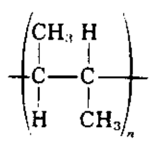


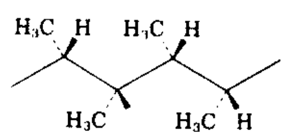
isotactic poly(oxypropylene)



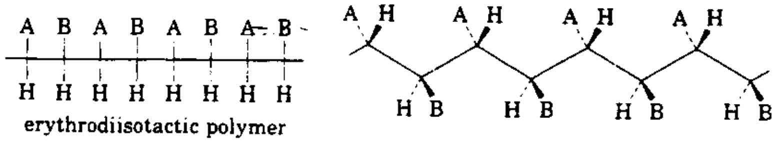


isotactic poly(ethylidene)

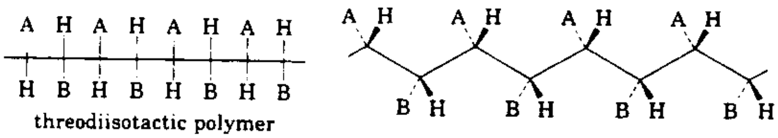




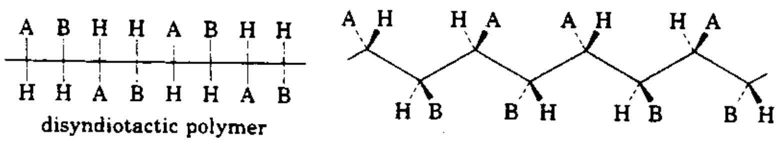
syndiotactic poly(ethylidene)



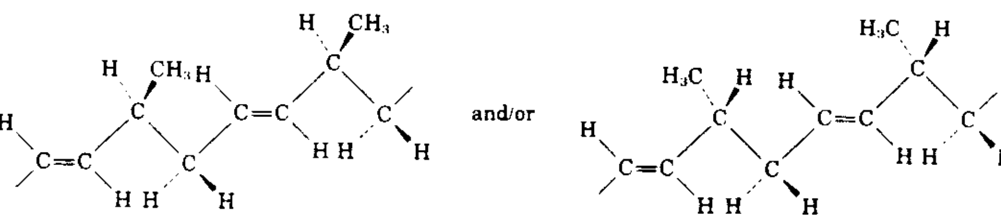
erythrodiisotactic polymer



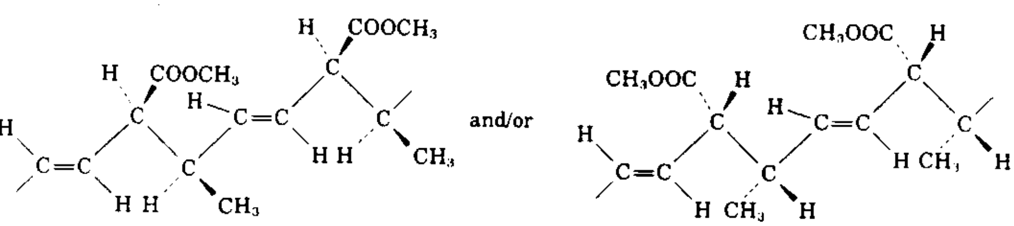
threodiisotactic polymer



disyndiotactic polymer

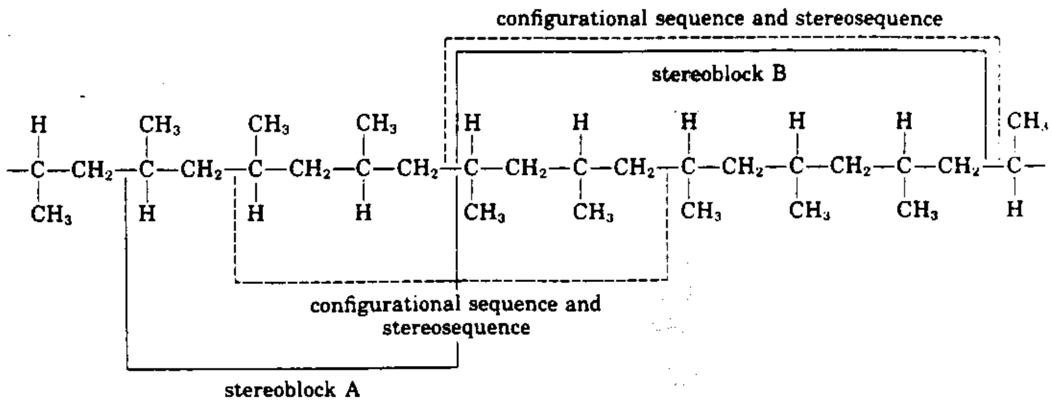


isotactic poly(3-methyl-*trans*-1-butenylene) or transisotactic poly(3-methyl-1-butenylene)



diisotactic poly[*threo*-3(methoxycarbonyl)-4-methyl-*trans*-1-butenylene] or
transthreodiisotactic poly[3-(methoxycarbonyl)-4-methyl-1-butenylene]

The concept of a stereoblock is illustrated in the following example of a regular poly(propylene) chain, in which the stereoblocks are denoted by ┌───┐. The sequence of identical relative configurations of adjacent units that characterizes a stereoblock is terminated at each end of the block. The dashed line ┌‐‐‐┐ encloses a configurational sequence, which may or may not be identical with a stereoblock.



The published IUPAC document (4) should be consulted for more complex cases and for the notations used to designate conformations of polymer molecules (bond lengths, bond angles, torsion angles, helix sense, isomorphous and enantiomorphous structures, line repetition groups and symmetry elements, etc) as well as for the various stereochemical definitions (see also MICROSTRUCTURE; STEREOREGULAR POLYMERS).

Trade Names and Abbreviations

Because the systematic names of polymers can be cumbersome, trade names and abbreviations are frequently used as a shortcut in industrial literature and

Table 4. List of Abbreviations from the 1986 IUPAC Recommendations[a]

PAN	polyacrylonitrile
PCTFE	polychlorotrifluoroethylene
PEO	poly(ethylene oxide)
PETP[b]	poly(ethylene terephthalate)
PE	polyethylene
PIB	polyisobutylene
PMMA	poly(methyl methacrylate)
POM	poly(oxymethylene); polyformaldehyde
PP	polypropylene
PS	polystyrene
PTFE	polytetrafluoroethylene
PVAC	poly(vinyl acetate)
PVAL	poly(vinyl alcohol)
PVC	poly(vinyl chloride)
PVDC	poly(vinylidene dichloride)
PVDF	poly(vinylidene difluoride)
PVF	poly(vinyl fluoride)

[a] Ref. 9.
[b] The abbreviation PET is commonly used in the literature.

oral communication. For example, the simpler generic name nylon-6,6 for a polyamide, where the first number refers to the number of carbon atoms of the diamine and the second number to that of the diacid fragment, appears often in the literature rather than the systematic name poly(iminoadipoyliminohexamethylene). Useful compilations of trade names for polymers can be found in Refs. 23 and 24.

Perhaps the most widely used shortcut is the use of abbreviations for common industrial polymeric materials. The IUPAC recognizes that there may be advantages in some cases to use abbreviations, but urges that each abbreviation be fully defined the first time it appears in the text and that no abbreviation be used in titles of publications. Because there are inherent difficulties in assigning systematic and unique abbreviations to polymeric structures, only a short list has the IUPAC's official sanction (9,10) (Table 4). ISO has published a more extensive list (25), and the American Chemical Society has compiled a master list of all known abbreviations in the polymer field (26).

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National Science Foundation
Secretary (1978–1987), IUPAC Commission on Macromolecular Nomenclature

NONAQUEOUS DISPERSIONS. See COATINGS.

NONCOMBUSTIBLE FABRICS. See FLAMMABILITY.

NONDESTRUCTIVE TESTING. See TEST METHODS.

NON-NEWTONIAN FLOW. See VISCOELASTICITY.

NONWOVEN FABRICS

SURVEY

Nonwoven fabrics are porous, textilelike materials, usually in flat she form, composed primarily or entirely of fibers assembled in webs (1–3). The fabrics, also called bonded fabrics, formed fabrics, or engineered fabrics, are ma ufactured by processes other than spinning, weaving, or knitting. The thickn of the sheets may vary from 25 μm to several centimeters, and the weight fr 10 g/m² to 1 kg/m². A sheet may resemble paper or a woven or knitted fabric appearance and may have a unique texture or pattern. It may be as compact a crisp as paper or supple and drapable as a conventional textile; it may be resili or limp. Its tensile properties may be barely self-sustaining or so high that i impossible to tear, abrade, or damage the sheet by hand. The fiber compone one or several types, may be natural or synthetic, from 1–3-mm long to endl The tensile properties may depend on frictional forces or a film-forming polym additive functioning as an adhesive binder. All or some of the fibers may welded by heat or solvent. A scrim, gauze, netting, yarn, or other conventi sheet material may be added to one or both faces, or embedded within as r forcement. The nonwoven fabric may be incorporated as a component in a c posite structure.

Felted fabrics from animal hairs, eg, wool (qv), are not included even th

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an·hy·drous \(ˈ)anˈhīdrəs\ *adj* [modif. (influenced by *hydr-*, *hydro-*) of Gk *anydros* waterless, fr. *an-* + *-ydros* (fr. *hydōr* water) — more at WATER] : destitute of water — used of water of crystallization, dissolved or combined water, adsorbed water

HERMES DECLARATION
EXHIBIT 11

Pure Appl. Chem., Vol. 73, No. 9, pp. 1511–1519, 2001.

INTERNATIONAL UNION OF PURE AND APPLIED CHEMISTRY

MACROMOLECULAR DIVISION
COMMISSION ON MACROMOLECULAR NOMENCLATURE*

GENERIC SOURCE-BASED NOMENCLATURE FOR POLYMERS

(IUPAC Recommendations 2001)

Prepared by a Working Group consisting of

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Generic source-based nomenclature for polymers

(IUPAC Recommendations 2001)

Abstract: The commission has already published two documents on the source-based names of linear copolymers and nonlinear polymers; however, in some cases this nomenclature leads to ambiguous names. The present document proposes a generic source-based nomenclature that solves these problems and yields clearer source-based names. A generic source-based name comprises two parts:

1) polymer class (generic) name followed by a colon
2) the actual or hypothetical monomer name(s), always parenthesized in the case of a copolymer

The formula, the structure-based name, the source-based name, and the generic source-based name of the polymer are given for each example in the document. In some cases, only generic source-based give unambiguous names, for example, when a polymer has more than one name or when it is obtained through a series of intermediate structures. The rules concern mostly polymers with one or more types of functional group or heterocyclic system in the main chain, but to some extent they are also applicable to polymers with side-groups, carbon-chain polymers such as vinyl or diene polymers, spiro and cyclic polymers, and networks.

CONTENTS

1. INTRODUCTION

The IUPAC Commission on Macromolecular Nomenclature has published three documents [1–3] on the structure-based nomenclature for polymers that enable most polymers, except networks, to be named. The Commission has also produced two documents [4,5] on the source-based nomenclature of linear copolymers and nonlinear polymers. In general, source-based names are simpler and less rigorous than structure-based names. However, there are cases in which the simplicity of the source-based nomenclature leads to ambiguous names for polymers. For example, the condensation of a dianhydride (A) with a diamine (B) gives first a polyamide-acid, which can be cyclized to a polyimide; however, both products have the same name poly(A-*alt*-B) according to current source-based nomenclature. If the class name of the polymer "amide-acid" or "imide" is incorporated in the name, differentiation is easily accomplished. Even in cases where only a single product is formed, use of the class name (generic name) may help to clarify the structure of the polymer, especially if it is very complex.

Examples of ambiguous names exist also for homopolymers. The source-based name "polybutadiene" does not indicate whether the structure is 1,2-, 1,4-*cis*-, or 1,4-*trans*-; supplementary information is needed to distinguish between the possibilities.

It is the objective of the present document to introduce a generic nomenclature system to solve these problems, and to yield better source-based names.

Most trivial names, such as polystyrene, are source-based names. Hitherto, the Commission has not systematically recommended source-based names for homopolymers because it considered that the more rigorous structure-based names were more appropriate for scientific communications. However, since the publication of "Nomenclature of Regular Single-Strand Organic Polymers" in 1976, scientists, in both industry and academia, have continued to use trivial names. Even the Commission itself adopted (1985) a source-based nomenclature for copolymers owing to its simplicity and practicality. Based on these facts, the Commission has now decided to recommend source-based nomenclature as an alternative official nomenclature for homopolymers. In this document, the rules for generating source-based names for homopolymers are described. Consequently, source-based and structure-based names are available for most polymers.

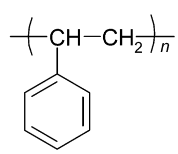
Names of the monomers in the source-based names of polymers should preferably be systematic but they may be trivial if well established by usage. Names of the organic groups, as parts of constitutional repeating units (CRU) in structure-based names, are those based on the principles of organic nomenclature and recommended by the 1993 *A Guide to IUPAC Nomenclature of Organic Compounds* [6].

2. SOURCE-BASED NOMENCLATURE FOR HOMOPOLYMERS

RULE 1

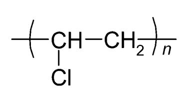
The source-based name of a homopolymer is made by combining the prefix "poly" with the name of the monomer. When the latter consists of more than one word, or any ambiguity is anticipated, the name of the monomer is parenthesized.

Example 1.1



Source-based name:
polystyrene
Structure-based name:
poly(1-phenylethylene)

Example 1.2



Source-based name:
poly(vinyl chloride)
Structure-based name:
poly(1-chloroethylene)

3. GENERIC NOMENCLATURE

3.1 Fundamental principles

The basic concept for generic source-based nomenclature is very simple; just add the polymer class name to the source-based name of the polymer. Addition of the polymer class name is frequently

OPTIONAL; in some cases, the addition is necessary to avoid ambiguity or to clarify. However, the addition is undesirable if it fails to add clarification.

The system presented here can be applied to almost all homopolymers, copolymers, and others, such as networks. However, generic source-based nomenclature should not be considered as a third nomenclature system to be added to the other two systems of nomenclature; it must be considered as an auxiliary system and a simple extension of current source-based nomenclature. When the generic part of the name is eliminated from the name of a polymer, the well-established source-based name remains.

3.2 General rules

RULE 2

A generic source-based name of a polymer has two components in the following sequence: (1) a polymer class (generic) name (polyG) followed by a colon and (2) the actual or hypothetical monomer name(s) (A, B, etc.), always parenthesized in the case of a copolymer. In the case of a homopolymer, parentheses are introduced when it is necessary to improve clarity.

polyG:A polyG:(B) polyG:(A-*co*-B) polyG:(A-*alt*-B)

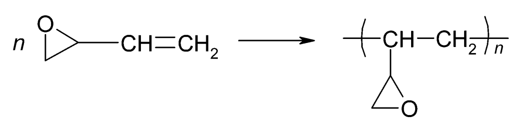
Note 1 The polymer class name (generic name) describes the most appropriate type of functional group or heterocyclic ring system.

Note 2 All the rules given in the two prior documents on source-based nomenclature [4,5] can be applied to the present nomenclature system, with the addition of the generic part of the name.

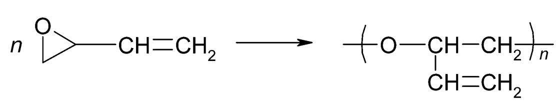
Note 3 A polymer may have more than one name; this usually occurs when it can be prepared in more than one way.

Note 4 If a monomer or a pair of complementary monomers can give rise to more than one polymer, or if the polymer is obtained through a series of intermediate structures, the use of generic nomenclature is essential (see examples 2.1, 2.3, and 2.4).

Example 2.1



I



II

Generic source-based name:

I. polyalkylene:vinyloxirane

II. polyether:vinyloxirane

Source-based names:

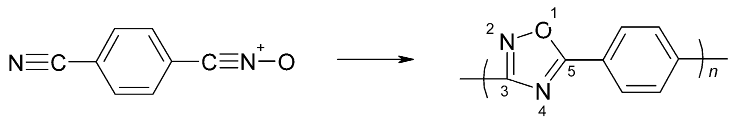
I and II have the same source-based name: poly(vinyloxirane).

Structure-based names:

I. poly(1-oxiranylethylene)

II. poly[(oxy(1-vinylethylene)]

Example 2.2



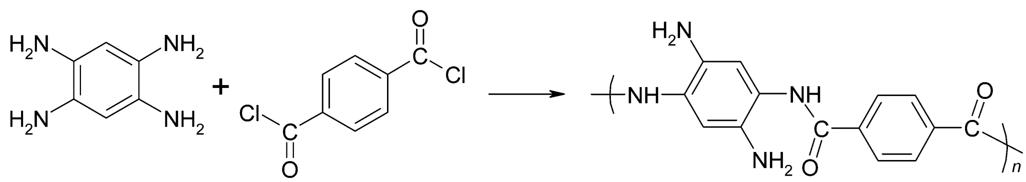
Generic source-based name:

polyoxadiazole:(4-cyanobenzonitrile *N*-oxide)

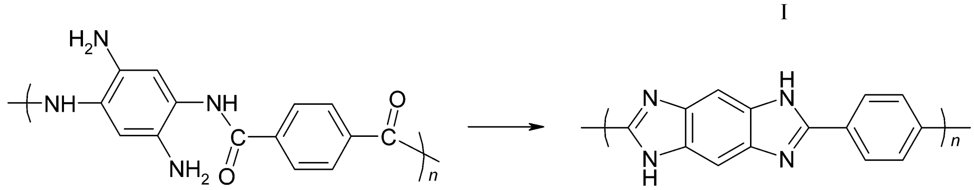
Structure-based name:

poly(1,2,4-oxadiazole-3,5-diyl-1,4-phenylene)

Example 2.3



I



I II

Generic source-based name:

I. polyamide:[(terephthaloyl dichloride)-*alt*-benzene-1,2,4,5-tetramine]

II. polybenzimidazole:[(terephthaloyl dichloride)-*alt*-benzene-1,2,4,5-tetramine]

Source-based name:

I and II have the same source-based name:

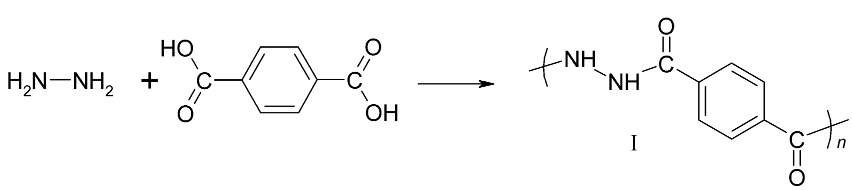
poly[(terephthaloyl dichloride)-*alt*-benzene-1,2,4,5-tetramine]

Structure-based names:

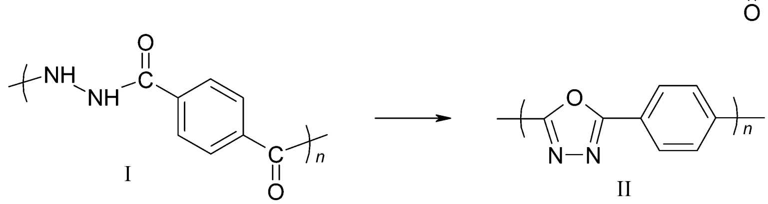
I. poly[imino (2,5-diamino-1,4-phenylene)iminoterephthaloyl]

II. poly[(1,5-dihydrobenzo[1,2-*d*:4,5-*d′*]diimidazole-2,6-diyl)-1,4-phenylene]

Example 2.4



I



I II

Generic source-based names:

I. polyhydrazide:[hydrazine-*alt*-(terephthalic acid)]

II. polyoxadiazole:[hydrazine-*alt*-(terephthalic acid)]

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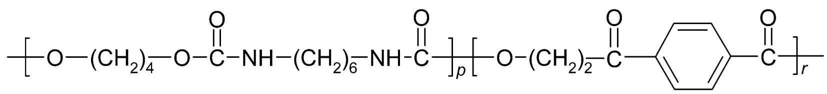
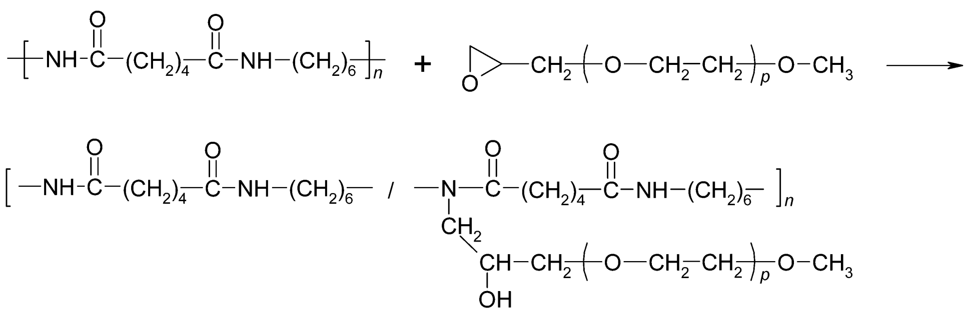
Source-based name:
I and II have the same source-based name: poly[hydrazine-*alt*-(terephthalic acid)]
Structure-based names:
I. poly(hydrazine-1,2-diylterephthaloyl)
II. poly(1,3,4-oxadiazole-2,5-diyl-1,4-phenylene)

Example 2.5



Generic source-based names:
polyurethane:[butane-1,4-diol-*alt*-(hexane-1,6-diyl diisocyanate)]-*block*-polyester:[(ethylene glycol)-*alt*-(terephthalic acid)]
Structure-based name:
poly(oxybutane-1,4-diyloxycarbonyliminohexane-1,6-diyliminocarbonyl)-*block*-poly(oxyethyleneoxyterephthaloyl)

Example 2.6



Generic source-based name:
polyamide:[hexane-1,6-diamine-*alt*-(adipic acid)]-*graft*-polyether:(ethylene oxide)

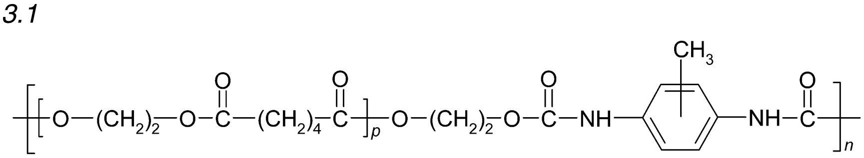
Note 5 It is assumed that this reaction is limited to only one graft for each CRU.

RULE 3

When more than one type of functional group or heterocyclic system is present in the polymer structure, names should be alphabetized; for example, poly(GG′):(A-*alt*-B).

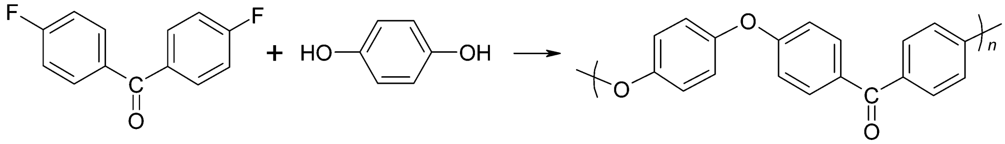
Note 6 It is preferable, but not mandatory, to cite all generic classes.

Example 3.1



Generic source-based name:
polyesterurethane:{α,ω-dihydroxyoligo[(ethylene glycol)-*alt*-(adipic acid)]-*alt*-(2,5-tolylene diisocyanate)}
Structure-based name:
poly{[oligo(oxyethyleneoxyadipoyl)]oxyethyleneoxycarbonylimino(x-methyl-1,4-phenylene)iminocarbonyl)}

Example 3.2



Generic source-based name:

polyetherketone:(4,4′-difluorobenzophenone-*alt*-hydroquinone)

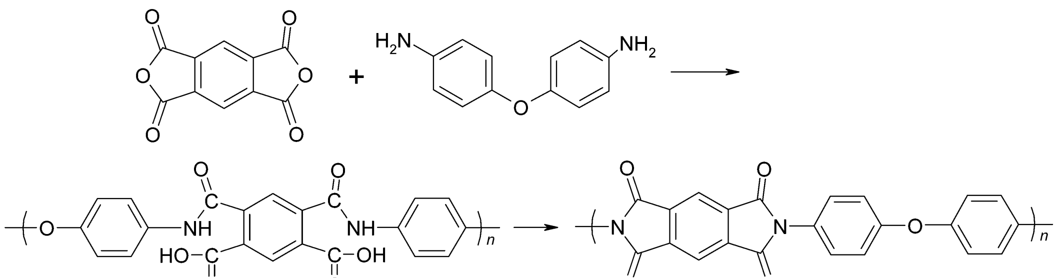
Structure-based name:

poly(oxy-1,4-phenyleneoxy-1,4-phenylenecarbonyl-1,4-phenylene)

RULE 4

Polymer class names relevant only to the main chain are specified in the name; names of side-chain functional groups may also be included after a hyphen if they are formed during the polymerization reaction.

Example 4.1



I II

Generic source-based names:

I. poly(amide-acid):[(pyromellitic dianhydride)-*alt*-(4,4′-oxydianiline)]
(Both carboxy groups result from the polymerization reaction.)

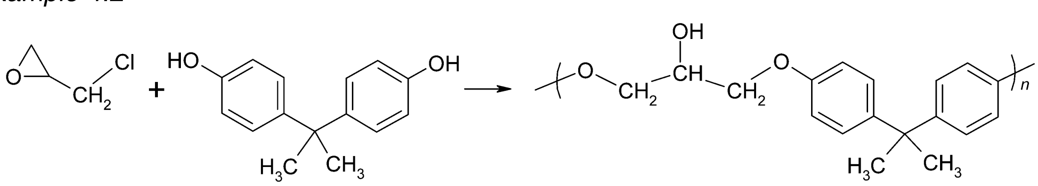
II. polyimide:[(pyromellitic dianhydride)-*alt*-(4,4′-oxydianiline)]

Structure-based names:

I. poly[oxy-1,4-phenyleneiminocarbonyl(4,6-dicarboxy-1,3-phenylene)carbonylimino-1,4-phenylene]

II. poly[(5,7-dihydro-1,3,5,7-tetraoxobenzo[1,2-*c*:4,5-*c*′]dipyrrole-2,6(1*H*,3*H*)-diyl)-1,4-phenyleneoxy-1,4-phenylene]

Example 4.2



Generic source-based names:

poly(ether-alcohol):(epichlorohydrin-*alt*-bisphenol A)

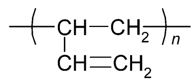
Structure-based name:

poly[oxy(2-hydroxypropane-1,3-diyl)oxy-1,4-phenylene(1-methylethane-1,1-diyl)-1,4-phenylene]

RULE 5

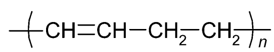
In the case of carbon-chain polymers such as vinyl polymers or diene polymers, the generic name is to be used only when different polymer structures may arise from a given monomeric system.

Example 5.1



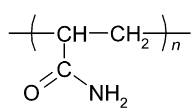
Generic source-based name:
    polyalkylene:(buta-1,3-diene)
Source-based name:
    poly(buta-1,3-diene)
Structure-based name:
    poly(1-vinylethylene)

Example 5.2



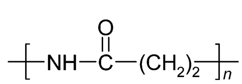
Generic source-based name:
    polyalkenylene:buta-1,3-diene
Source-based name:
    poly(buta-1,3-diene)
Structure-based name:
    poly(but-1-ene-1,4-diyl)

Example 5.3



Generic source-based name:
    polyalkylene:acrylamide
Structure-based name:
    poly[1-(aminocarbonyl)ethylene]

Example 5.4



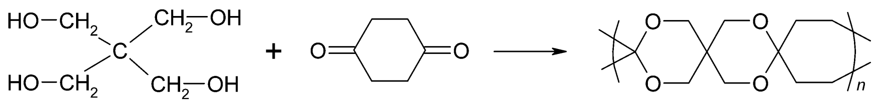
Generic source-based name:
    polyamide:acrylamide
Structure-based name:
    poly[imino(1-oxopropane-1,3-diyl)]

Note 7 The terms polyalkylene and polyalkenylene have been defined in ref. 7, p. 149.

4. FURTHER APPLICATIONS OF GENERIC NAMES

Generic source-based nomenclature can be extended to more complicated polymers such as spiro and cyclic polymers and networks.

Example 6.1



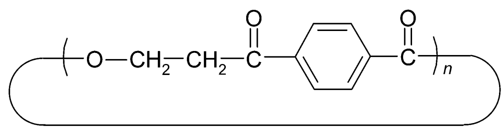
Generic source-based name:

polyspiroketal:{[2,2-bis(hydroxymethyl)-propane-1,3-diol]-*alt*-cyclohexane-1,4-dione}
or polyspiroketal:(pentaerythritol-*alt*-cyclohexane-1,4-dione)

Structure-based name:

poly[2,4,8,10-tetraoxaspiro[5.5]undecane-3,3,9,9-tetrayl-9,9-bis(ethylene)]

Example 6.2

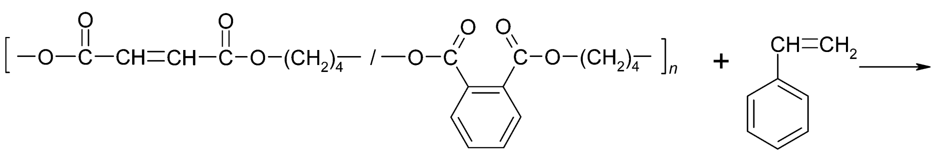


Generic source-based name:

cyclo-polyester:[(ethylene glycol)-*alt*-(terephthalic acid)]

Note 8 There is no IUPAC nomenclature for cyclic polymers.

Example 6.3



Generic source-based name:

polyester:{butane-1,4-diol-*alt*-[(maleic anhydride);(phthalic anhydride)]}-*net*-polyalkylene:(maleic anhydride)-*co*-styrene]

5. REFERENCES

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HERMES DECLARATION
EXHIBIT 12

SALES BULLETIN

DATE **01/05/05** SUBJECT **High Strength Sutures** NUMBER **UE133**

A Biomechanical Analysis of High Strength Sutures

Recently, Stephen S. Burkhart, M.D., conducted a biomechanical analysis of new high strength sutures used primarily for arthroscopic shoulder surgery. The purpose of the study was to determine the type of braided suture that produces the optimal knot configuration maximizing both knot and loop security. The high strength sutures tested were #2 FiberWire®, #2 OrthoCord™, Herculine™, MaxBraid, UltraBraid™, and Ethibond™ (2 mm FiberTape™ was also included in this study).

Conclusions

- Tying a surgeon's knot with #2 FiberWire significantly increases knot security compared to #2 OrthoCord, #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond.
- Tying a surgeon's knot or sliding knot with #2 FiberWire provides the optimum balance of loop and knot security compared to #2 OrthoCord, #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond.
- #2 FiberWire provides the greatest loop security when tying a Weston or Roeder knot compared to #2 OrthoCord, #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond.
- #2 FiberWire has the greatest knot security when tying a surgeon's knot compared to #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond. Although #2 OrthoCord had the smallest loop circumference when tying a surgeon's knot the difference between the loop circumference of #2 FiberWire and #2 OrthoCord **was not** statistically significant.
- In straight pull-testing, #2 FiberWire had the highest ultimate strength compared to #2 OrthoCord, #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond.
- #2 FiberWire had the smallest percentage of elongation compared to #2 OrthoCord, #2 Herculine, #2 MaxBraid, #2 UltraBraid, and #2 Ethibond.

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Methods & Materials

Six #2 sutures were tested, FiberWire (polyethylene & polyester), Ethibond (polyester), OrthoCord (polydioxnone & polyester), Herculine (polyethylene), MaxBraid (polyethylene), and UltraBraid (polyethylene with & without a monofilament polypropylene marker). Three knots were used, the Roeder & Weston knots with three reversing half-hitches on alternating posts as well as a static surgeon's knot. Additionally, 2 mm FiberTape (polyethylene & polyester) were tied using four alternating throws. All total 133 knots were tied.

All knots were tied around a 30 mm circumference post to assure consistent loop circumference by Stephen S. Burkhart, M.D., a senior arthroscopic surgeon (Figure 1). Before testing, the knot stack was measured using calipers (Figure 2).

ARM 002188

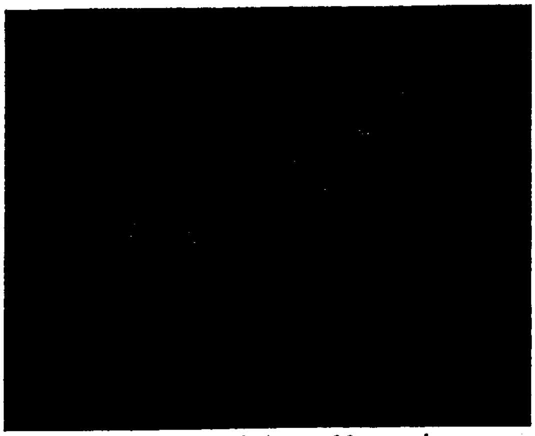


Figure 1: Knot tied over 30 mm pin.

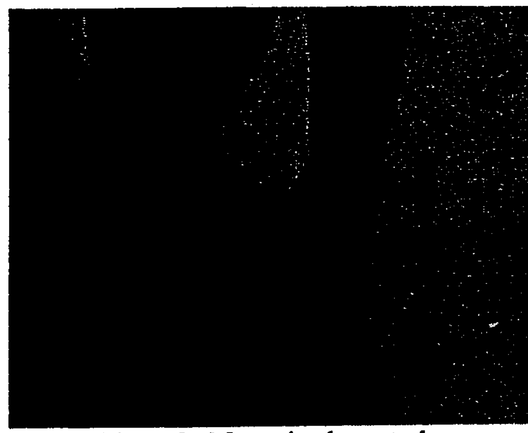


Figure 2: Measuring knot stack.

Each loop was mounted on an Instron materials testing system (model 5544, Instron, Canton, MA) to test knot and loop security. Fixtures were mounted to the base and crosshead of the Instron with two 3.95 mm diameter rods held parallel. Each loop was placed around the rods with the knots centered between the two rods (Figure 3). A 5N preload was applied at 1 mm/s and then pulled to failure at 1 mm/s. Data was collected at 500 Hz.

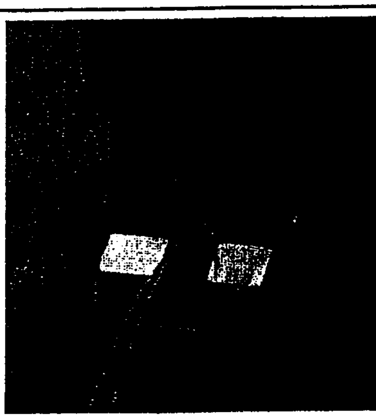


Figure 3: Instron test set up.

The loop circumference was measured at the 5N preload to assess each knot's ability to maintain a tight loop without slippage (loop security). The loop circumference was calculated based on equation 1 where C_l = loop circumference, d = rod diameter, and x = crosshead displacement measured for the center of each rod.

Equation 1: $C_l = \pi d \times 2(x)$

Knot security was measured as the maximum force to failure at 3 mm of crosshead displacement or suture breakage during single pull load testing (force to failure and failure mode were recorded). Three millimeters of elongation was selected as the failure mode because 3 mm or more is generally accepted in the literature. For statistical analysis one way analyses of variance (ANOVA) were used. *Post hoc* pairwise multiple comparisons were made using a Biferroni t-test. A significance level of 0.05 was used for all analyses.

HERMES DECLARATION
EXHIBIT 13

Arthrex, Inc., Naples, FL
Test Report Summary and Sign-Off Sheet

Ref: RAF-04.16-1
Rev: 3
Date: 01/08/04
Approved DCN: 03310

Test Report: # TEST021104

Part number:	Rev:	Description:	Material:
DT PS05 T2	N/A	#2 Fiberwire MED2174 Coated and Uncoated USIPG Dyed	Polyethylene, Polyester
Vendor Name: Pearsalls Brian Hallett.		**Lot Numbers:** N/A	**Number Tested:** 3/2
Performed by: Ashley Holloway		**Type of Test:** Knot Tiedown	**Date:** 02/16/04

Test Objective:

To determine the peak force required to advance a single half hitch using coated and uncoated Fiberwire suture.

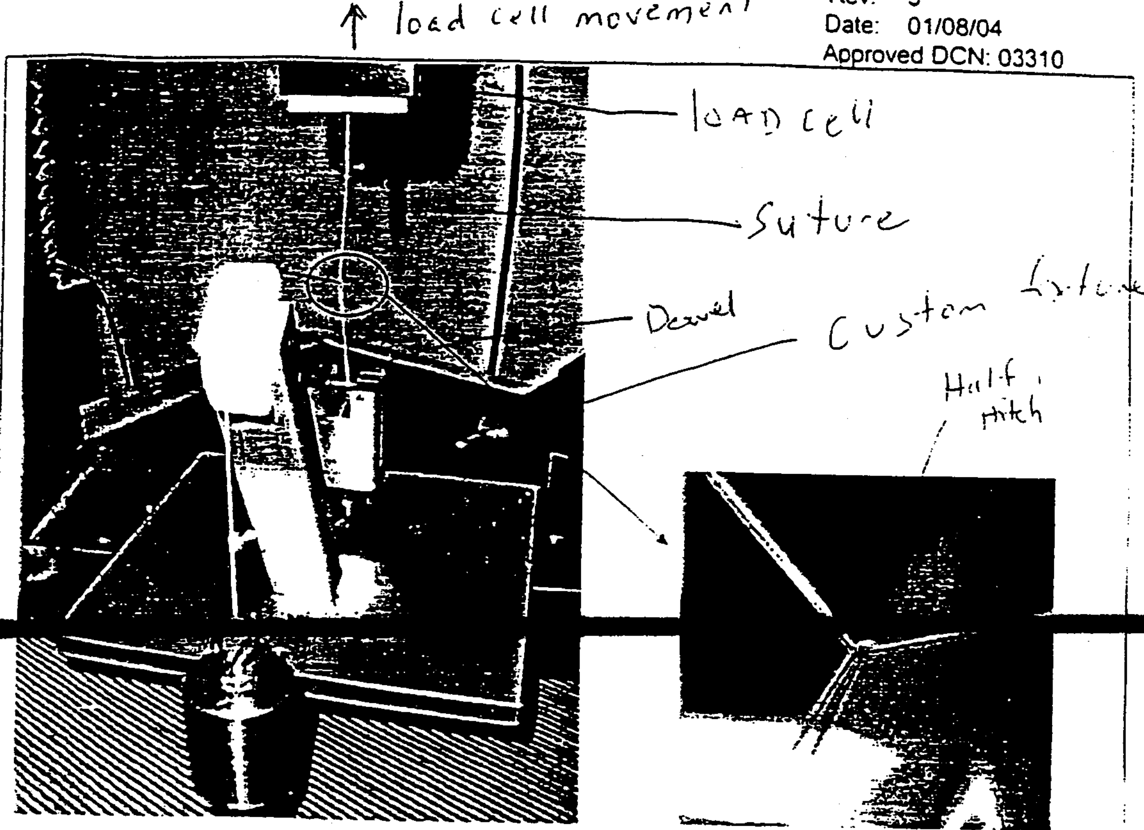
Materials and Methods:

The 50lb load cell was attached to the MTS Sintech 1/S and calibrated. A custom fixture as shown was used to simulate knot tying that would occur clinically. The top end of the suture was clamped in a custom fixture that was attached to the load cell, and then a single half hitch was tied around a guide block such that the loop length was consistent between samples. A weight of .375 kg was then attached to the free end of the suture in order to tension the loop. Care was taken to tension the legs of the suture consistently. The loop was then loaded at 12 in/min for 30mm and data was collected at 200 Hz. The peak load required to cause the half hitch to slip was recorded and used for data analysis purposes.

DEPUY MITEK
EXHIBIT 343
04cv12457

Arthrex, Inc., Naples, FL
Test Report Summary and Sign-Off Sheet

Ref: RAF-04.16-1
Rev: 3
Date: 01/08/04
Approved DCN: 03310



Data Analysis/Conclusions:

A mean peak force of 12.7 N was recorded for the coated suture. This force represents the force required to initiate slippage of the half hitch. A mean peak force of 32.9 N was recorded for the uncoated suture. A significantly greater amount of force was required to advance the uncoated suture.

2/16/04

Sample ID: coated_uncoated suture_1_021004.mss
Method: Suture Test.msm

Test Date: 2/11/04
Operator: Ashley Holloway

Sample Information:

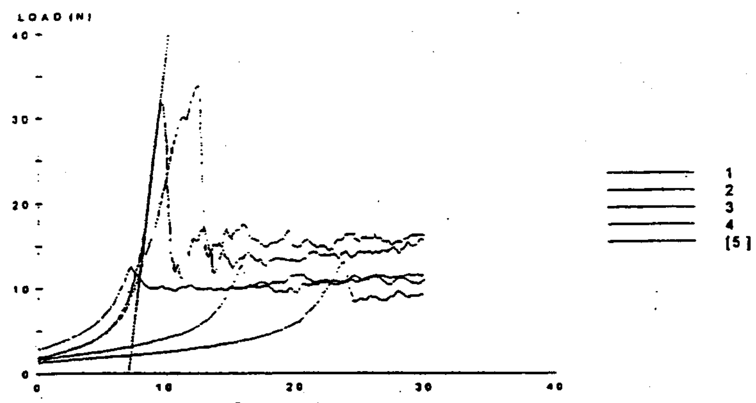
Name	Value
Lot Number	n/a
Part Number	Coated/Uncoated suture test
Revision Level	#2 Fiberwire

Specimen Results:

Specimen #	Peak Load Coated (N)		Specimen #	Peak Load Noncoated (N)
1	12.43		4	34.04
2	13.08		5	31.71
3	12.64			
Mean	12.72			32.88
Std. Dev.	0.33			1.65
Minimum	12.43			31.71
Maximum	13.08			34.04

Calculation Inputs:
Test Inputs:

Name	Value	Units
Break Threshold	5.620	lbf
Brk Sensitivity	95	%
Data Acq. Rate	200.0	Hz
Ext Limit HI	30.0	mm
Initial Speed	300.00	mm/min
Load Limit HI	150	N
MaxSpecimens	999	
Outer Loop Rate	100	Hz
Slack Pre-Load	5.00	N
Slowdown Extension	0.000	in
Slowdown Load	0.000	lbf
Slowdown Strain	0.000	%
Test Speed	305.00	mm/min



HERMES DECLARATION
EXHIBIT 14

(12) UK Patent Application (19) GB (11) 2 218 312 (13) A

(43) Date of A publication 15.11.1989

(21) Application No 8911088.6

(22) Date of filing 15.05.1989

(30) Priority data
(31) 8811498 (32) 14.05.1988 (33) GB

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(51) INT CL⁴
A01K 91/00, D04C 1/12

(52) UK CL (Edition J)
A1A A19
D1K K14
U1S S1022

(56) Documents cited
None

(58) Field of search
UK CL (Edition J) A1A, D1K
INT CL⁴ A01K, D04C

(54) Improvements relating to fishing lines

(57) A fishing line of braided construction has some filaments of high tensile polythene. The other filaments are of polyester and/or nylon, and the braid may be coated with a sheath of polyurethane.

GB 2 218 312 A

"Improvements relating to Fishing Lines"

This invention relates to fishing lines.

Fishing lines require many qualities, such as high tensile strength, while having a small diameter, non-stretchability, resistance to abrasion, smooth running and suppleness. It is the aim of this invention to provide a line embodying most of these not usually very compatible properties.

According to the present invention there is provided a fishing line of braided construction, some braid filaments being of high tensile polythene thread and other filaments being of polyester and/or nylon.

The high tensile polythene gives the line minimal stretchability and will preferably be a high molecular weight polythene, melted in a solvent and drawn at high speed into extremely fine strands. This produces almost perfect alignment of all the molecules in long chains. A suitable product is that sold under the Registered Trade Mark DYNEEMA.

With polyester, multifilaments will generally be used, and the more there are of them in proportion to the polythene the stiffer the line will be. With nylon, monofilaments will preferably be used and the principal effect will be a low coefficient of friction.

It would be possible for certain applications to combine both polyester and nylon with the polythene thread.

The braid may be coated with a thin, supple and smooth sheath of polyurethane and this may be carried out by a simple immersion process in liquid polyurethane. It will alter the characteristics (such as buoyancy and strength) in a predictable manner, but its main purpose is to prevent saturation of the interstices of the braid. In very cold conditions, such as fishing through holes in ice, water having worked its way into the braid will freeze and impart a brittleness that can lead to breakage.

CLAIMS

1. A fishing line of braided comnstruction, some braid filaments being of high tenazile polythene thread and other filaments being of pollyester and/or nylon.

2. A line as claimed in Claim 1,, wherein the other filaments include polyester maulti-filaments.

3. A line as claimed in Claim 1 or 2, wherein the other filaments include nylon monorfilaments.

4. A line as claimed in Claim 1., 2 or 3, wherein the braid is coated by a sheath of polyyurethane.

5. A line as claimed in any preeceding Claim, wherein the polythene is that sold undeer the Trade Mark DYNEEMA.

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